

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-41567

ProSomnus, Inc.

(Exact name of registrant as specified in its charter)

DE
(State or other jurisdiction of
incorporation or organization)

88-2978216
(I.R.S. Employer
Identification Number)

5675 Gibraltar Drive
Pleasanton, CA 94588
(Address of Principal Executive Offices)
(844) 537-5337
(Registrant's telephone number)

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

Title of Each Class	Trading symbol	Name of Exchange on which registered
Common Stock, par value \$0.0001 per share	OSA	The Nasdaq Global Market
Warrants, each whole warrant exercisable for one share of Common Stock for \$11.50 per share	OSAAW	The Nasdaq Global Market

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

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

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

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

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

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

As of November 13, 2023, there were 16,398,599 of the registrant's ordinary shares outstanding.

TABLE OF CONTENTS

PROSOMNUS, INC.

	<u>Page</u>
Part I	Financial Information
Item 1.	Financial Statements (Unaudited)
	1
	Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022
	1
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2023 and 2022
	2
	Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit for the three and nine months ended September 30, 2023
	3
	Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit for the three and nine months ended September 30, 2022
	4
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022
	5
	Notes to Condensed Consolidated Financial Statements
	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
	25
Item 3.	Quantitative and Qualitative Disclosures about Market Risk
	33
Item 4.	Controls and Procedures
	34
Part II	Other Information
	35
Item 1.	Legal Proceedings
	35
Item 1A.	Risk Factors
	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds
	59
Item 3.	Defaults Upon Senior Securities
	59
Item 4.	Mine Safety Disclosures
	59
Item 5.	Other Information
	59
Item 6.	Exhibits
	60
Exhibit Index	60
Signatures	62

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROSOMNUS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,021,908	\$ 15,916,141
Accounts receivable, net	3,443,306	2,843,148
Inventory	1,650,097	639,945
Prepaid expenses and other current assets	557,561	1,846,870
Total current assets	17,672,872	21,246,104
Property and equipment, net	3,739,621	2,404,402
Finance lease right-of-use assets	3,532,240	3,650,451
Operating lease right-of-use assets	5,154,399	5,632,771
Other assets	284,000	262,913
Total assets	\$ 30,383,132	\$ 33,196,641
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,747,841	\$ 2,101,572
Accrued expenses	8,373,482	3,706,094
Equipment financing obligation	55,510	58,973
Finance lease liabilities	1,109,899	1,008,587
Operating lease liabilities	290,869	215,043
Total current liabilities	11,577,601	7,090,269
Equipment financing obligation, net of current portion	143,498	185,645
Finance lease liabilities, net of current portion	2,226,908	2,081,410
Operating lease liabilities, net of current portion	5,267,969	5,525,562
Senior Convertible Notes at fair value	13,286,405	13,651,000
Subordinated Convertible Notes at fair value	18,720,000	10,355,681
Earnout liability	730,000	12,810,000
Warrant liability	134,043	1,991,503
Total noncurrent liabilities	40,508,823	46,600,801
Total liabilities	52,086,424	53,691,070
Commitments and contingencies		
Redeemable Series A Preferred Stock, \$0.0001 par value, stated value \$1,000; 25,000 shares authorized at September 30, 2023; 9,526 shares issued and outstanding at September 30, 2023; liquidation preference of \$14,289 at September 30, 2023; No shares authorized, issued and outstanding at December 31, 2022	11,664,989	—
Stockholders' deficit:		
Preferred stock, \$0.0001 par value, 975,000 and 1,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; no shares issued and outstanding	—	—
Common Stock, \$0.0001 par value, 100,000,000 shares authorized; 16,288,124 and 16,041,464 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1,629	1,604
Additional paid-in capital	194,650,729	190,298,562
Accumulated deficit	(228,020,639)	(210,794,595)
Total stockholders' deficit	(33,368,281)	(20,494,429)
Total liabilities and stockholders' deficit	\$ 30,383,132	\$ 33,196,641

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

PROSOMNUS, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 7,071,445	\$ 4,997,979	\$ 19,813,735	\$ 13,601,031
Cost of revenue	3,580,073	2,540,288	9,507,498	6,440,475
Gross profit	3,491,372	2,457,691	10,306,237	7,160,556
Operating expenses:				
Sales and marketing	3,240,511	2,319,362	9,707,277	6,450,173
Research and development	1,040,065	688,540	3,435,070	1,915,521
General and administrative	3,426,872	1,577,049	11,260,003	4,219,938
Total operating expenses	7,707,448	4,584,951	24,402,350	12,585,632
Net loss from operations	(4,216,076)	(2,127,260)	(14,096,113)	(5,425,076)
Other income (expense)				
Interest expense, net	(1,489,286)	(1,421,702)	(3,901,255)	(3,714,777)
Change in fair value of earnout liability	3,880,000	—	12,080,000	—
Change in fair value of debt	3,699,737	—	1,070,307	—
Change in fair value of warrant liability	593,621	—	1,857,460	(20,756)
Loss on debt extinguishment	(9,743,043)	—	(9,743,043)	(192,731)
Other expense	(3,963,756)	—	(4,493,400)	—
Total other income (expense), net	(7,022,727)	(1,421,702)	(3,129,931)	(3,928,264)
Net loss before income taxes	(11,238,803)	(3,548,962)	(17,226,044)	(9,353,340)
Net loss	<u>\$ (11,238,803)</u>	<u>\$ (3,548,962)</u>	<u>\$ (17,226,044)</u>	<u>\$ (9,353,340)</u>
Net loss per share attributable to Common Stockholders, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.14)</u>	<u>\$ (1.07)</u>	<u>\$ (0.38)</u>
Weighted average shares attributable to Common Stockholders, basic and diluted	<u>16,115,254</u>	<u>24,713,218</u>	<u>16,071,719</u>	<u>24,611,666</u>

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

PROSOMNUS, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK
AND STOCKHOLDERS' DEFICIT (UNAUDITED)
For the three and nine months ended September 30, 2023**

	Three Months Ended September 30, 2023						
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series A						
	Shares	Amount	Shares	Amount			
Balance as of June 30, 2023	—	\$ —	16,057,630	\$ 1,606	\$ 191,031,730	(\$ 216,781,836)	(\$ 25,748,500)
Conversion of Subordinated Convertible Notes	—	—	230,494	23	919,546	—	919,569
Issuance of Series A Convertible Preferred Stock	9,526	11,664,989	—	—	—	—	—
Issuance of Common Stock warrants	—	—	—	—	2,552,857	—	2,552,857
Stock-based compensation expense	—	—	—	—	146,596	—	146,596
Net loss	—	—	—	—	—	(11,238,803)	(11,238,803)
Balance as of September 30, 2023	9,526	\$ 11,664,989	16,288,124	\$ 1,629	\$ 194,650,729	(\$ 228,020,639)	(\$ 33,368,281)

	Nine Months Ended September 30, 2023						
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series A						
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2022	—	\$ —	16,041,464	\$ 1,604	\$ 190,298,562	(\$ 210,794,595)	(\$ 20,494,429)
Issuance of shares, net of cancellations and issuance costs	—	—	16,166	2	163,571	—	163,573
Conversion of Subordinated Convertible Notes	—	—	230,494	23	919,546	—	919,569
Issuance of Series A Convertible Preferred Stock	9,526	11,664,989	—	—	—	—	—
Issuance of Common Stock warrants	—	—	—	—	2,552,857	—	2,552,857
Stock-based compensation expense	—	—	—	—	716,193	—	716,193
Net loss	—	—	—	—	—	(17,226,044)	(17,226,044)
Balance as of September 30, 2023	9,526	\$ 11,664,989	16,288,124	\$ 1,629	\$ 194,650,729	(\$ 228,020,639)	(\$ 33,368,281)

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

**CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK
AND STOCKHOLDERS' DEFICIT (UNAUDITED)
For the three and nine months ended September 30, 2022**

	Three Months Ended September 30, 2022								
	Redeemable Convertible Preferred Stock				Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series B		Series A						
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of June 30, 2022	7,288,333	\$ 12,389,547	26,245	\$ 26,245,000	24,702,891	\$ 2,469	\$ 150,429,947	(\$ 209,453,653)	(\$ 59,021,237)
Vesting of restricted stock awards	—	—	—	—	79,031	8	(8)	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,000	—	1,000
Net loss	—	—	—	—	—	—	—	(3,548,962)	(3,548,962)
Balance as of September 30, 2022	7,288,333	\$ 12,389,547	26,245	\$ 26,245,000	24,781,922	\$ 2,477	\$ 150,430,939	(\$ 213,002,615)	(\$ 62,569,199)

	Nine Months Ended September 30, 2022								
	Redeemable Convertible Preferred Stock				Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series B		Series A						
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	7,288,333	\$ 12,389,547	26,245	\$ 26,245,000	24,566,386	\$ 2,456	\$ 150,425,960	(\$ 203,649,275)	(\$ 53,220,859)
Vesting of restricted stock awards	—	—	—	—	215,536	21	(21)	—	—
Stock-based compensation expense	—	—	—	—	—	—	5,000	—	5,000
Net loss	—	—	—	—	—	—	—	(9,353,340)	(9,353,340)
Balance as of September 30, 2022	7,288,333	\$ 12,389,547	26,245	\$ 26,245,000	24,781,922	\$ 2,477	\$ 150,430,939	(\$ 213,002,615)	(\$ 62,569,199)

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

PROSOMNUS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (17,226,044)	\$ (9,353,340)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	578,503	302,932
Reduction of finance right-of-use asset	681,763	597,904
Reduction of operating right-of-use asset	286,337	131,090
Loss on debt extinguishment	9,743,043	192,731
Loss on financing transactions	2,472,915	—
Noncash interest	2,528,106	2,934,254
Amortization of debt financing costs	1,468,497	135,956
Loss on disposal of property and equipment	117,449	—
Bad debt expense	87,181	54,448
Stock-based compensation	716,193	5,000
Shares issued for services received	163,573	—
Change in fair value of earnout liability	(12,080,000)	—
Change in fair value of debt	(1,070,307)	—
Change in fair value of warrant liability	(1,857,460)	20,756
Impairment of assets	682,126	—
Other	100,000	—
Changes in operating assets and liabilities:		
Accounts receivable	(687,339)	(296,524)
Inventory	(1,010,152)	(26,936)
Prepaid expenses and other current assets	1,061,382	(319,416)
Deferred financing costs	—	(1,807,626)
Other assets	(21,087)	(108,117)
Accounts payable	(472,438)	2,195,139
Accrued expenses	3,384,095	854,915
Operating lease liabilities	38,101	(148,486)
Commission settlement	—	(127,074)
Net cash used in operating activities	(10,315,563)	(4,762,394)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,903,242)	(331,373)
Net cash used in investing activities	(1,903,242)	(331,373)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Series A Preferred Stock and warrants	9,526,000	—
Principal payments on finance lease obligations	(1,026,701)	(822,315)
Principal payments on equipment financing obligation	(45,610)	(41,728)
Payment of debt financing costs	(129,117)	—
Proceeds from subscription agreements	—	1,225,000
Proceeds from line of credit	—	18,759,540
Repayments of line of credit	—	(17,587,978)
Proceeds from issuance of subordinated notes	—	375,000
Repayments of subordinated notes	—	(75,000)
Repayments of subordinated loan and security agreement	—	(710,320)
Proceeds from issuance of unsecured subordinated promissory notes	—	5,131,789
Repayments of unsecured subordinated promissory notes	—	(500,000)
Net cash provided by financing activities	8,324,572	5,753,988
Net change in cash, cash equivalents, and restricted cash	(3,894,233)	660,221
Cash, cash equivalents, and restricted cash at beginning of period	15,916,141	1,500,582
Cash, cash equivalents, and restricted cash at end of period	\$ 12,021,908	\$ 2,160,803
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,134,832	\$ 559,230
Cash paid for franchise taxes	\$ 800	\$ 6,480
Supplemental disclosure of noncash investing and financing activities:		
ROU assets obtained in exchange for finance lease obligations	\$ 1,273,511	\$ —
Acquisition of property and equipment through finance leases	\$ —	\$ 1,560,520
Addition of ROU assets from finance lease modification	\$ —	\$ 239,000
Conversion of Subordinated Convertible Notes to common stock	\$ 919,546	\$ —

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

PROSOMNUS, INC.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)**

NOTE 1 — DESCRIPTION OF THE BUSINESS

Company Organization

ProSomnus, Inc., and its wholly owned subsidiaries, ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc. (collectively, the “Company”) is an innovative medical technology company that develops, manufactures, and markets its proprietary line of precision intraoral medical devices for treating and managing patients with obstructive sleep apnea (“OSA”).

The Company is located in Pleasanton, California and was incorporated as a Delaware company on May 3, 2022. Its accounting predecessor company, ProSomnus Sleep Technologies, Inc. was incorporated as a Delaware company on March 2, 2016.

NOTE 2 — BASIS OF ACCOUNTING AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries and have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) and in conjunction with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Certain information and footnote disclosures required for annual financial statements have been condensed or excluded in accordance with SEC rules and regulations and GAAP applicable to interim unaudited financial statements. Accordingly, the condensed consolidated financial statements do not include all of the information and footnotes required by GAAP for audited annual financial statements. In the opinion of management, the condensed consolidated financial statements reflect all adjustments of a normal and recurring nature that are considered necessary for a fair presentation of the results for the interim periods presented. These unaudited condensed consolidated financial statements and the accompanying notes should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on April 14, 2023.

The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or any future periods. The condensed consolidated balance sheet as of December 31, 2022 has been derived from audited financial statements at that date but does not include all of the information required by GAAP for complete financial statements.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Liquidity and Management’s Plans

The Company has incurred recurring losses from operations and recurring negative cash flows from operating activities. The Company expects operating losses and negative cash flows from operations to continue for the foreseeable future.

The Company’s ability to continue as a going concern depends on its ability to execute on its plans to achieve revenue growth forecast, control operating costs, and obtain additional financing. The Company has developed a cash flow breakeven plan pursuant to which the Company expects to maintain positive cash balances and compliance with its debt covenants and commitments. The Company has commenced the implementation of its plan and believes the plan, when fully implemented as planned, will mitigate the liquidity risks identified. However, the Company’s operating plan may change as a result of many factors currently unknown and there can be no assurance that the current operating plan or cash flow break even plan will be achieved in the time frame anticipated by the Company.

Furthermore, there can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all.

Based on the Company's current level of expenditures and management's future cash flow projections, the Company believes its cash and cash equivalents of \$12.0 million and working capital of \$6.1 million at September 30, 2023, may not be sufficient for the Company to continue operations as a going concern for at least one year from the issuance date of these condensed consolidated financial statements. Additionally, from July 1, 2023, the Convertible Notes (as defined in Note 7) require the Company to maintain a minimum cash balance of \$4.5 million on the first of each calendar month. The Company believes that without the successful and full implementation of its cash flow breakeven plan, these factors raise substantial doubt about its ability to continue as a going concern.

The accompanying condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and disclosure of contingent assets and liabilities. Actual results could differ from these estimates, and such differences could materially affect the results of operations reported in future periods. The Company's significant estimates in these condensed consolidated financial statements relate to the fair values, and the underlying assumptions used to formulate such fair values, of its Series A Preferred Stock, Convertible Notes, earn-out liability, and warrants. Estimates also include the allowance for doubtful accounts receivable, warranty and earned discount accruals, measurements of tax assets and liabilities and stock-based compensation.

Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. Fair value is defined as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date.

This accounting standard establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs that may be used to measure fair value:

Level 1 Inputs — The valuation is based on quoted prices in active markets for identical instrument.

Level 2 Inputs — The valuation is based on observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model — based valuation techniques for which all significant assumptions are observable in the market.

Level 3 Inputs — The valuation is based on unobservable inputs that are supported by minimal or *no* market activity and that are significant to the fair value of the instrument. Level 3 valuations are typically performed using pricing models, discounted cash flow methodologies, or similar techniques that incorporate management's own estimates of assumptions that market participants would use in pricing the instrument, or valuations that require significant management judgment or estimation.

Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate.

The Company's financial instruments consist primarily of cash equivalents, accounts receivable (net of allowance for doubtful accounts), accounts payable and accrued expenses, long-term debt instruments, earnout and warrant liabilities. The carrying values of our working capital balances are representative of their fair values due to their short-term maturities.

[Table of Contents](#)

The carrying value of our equipment financing obligation is considered to approximate its fair value because the interest rate is comparable to current rates for financing available to us. Under the fair value option as prescribed by Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 825, *Financial Instruments*, we have elected to record our convertible debt instruments at fair value. The earnout and warrant liabilities are presented at fair value on the condensed consolidated balance sheets.

The following tables provide a summary of the financial instruments that are measured at fair value on a recurring basis:

	Fair Value	September 30, 2023		
		Level 1	Level 2	Level 3
Senior Convertible Notes	\$ 13,286,405	\$ —	\$ —	\$ 13,286,405
Subordinated Convertible Notes	18,720,000	—	—	18,720,000
Earnout liability	730,000	—	—	730,000
Warrant liability	134,043	—	—	134,043

	Fair Value	December 31, 2022		
		Level 1	Level 2	Level 3
Senior Convertible Notes	\$ 13,651,000	\$ —	\$ —	\$ 13,651,000
Subordinated Convertible Notes	10,355,681	—	—	10,355,681
Earnout liability	12,810,000	—	—	12,810,000
Warrant liability	1,991,503	—	—	1,991,503

A financial instrument’s level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement.

Cash and Cash Equivalents

The Company considers all demand deposits with an original maturity to the Company of 90 days or less as cash and cash equivalents. The Company places its cash and cash equivalents with high credit-quality financial institutions. As of September 30, 2023 and December 31, 2022, the Company had \$12.0 million and \$15.9 million of cash and no cash equivalents, respectively, which includes restricted cash of \$0.7 million at September 30, 2023 consisting of a letter of credit on hand with the Company’s financial institution as collateral for an office lease.

Convertible Notes

The Company accounts for its Senior Convertible Notes and Subordinated Convertible Notes (as defined below), as derivatives in accordance with, ASC 815-10, Derivatives and Hedging, and ASC 815-15, Embedded Derivatives, depending on the nature of the derivative instrument. ASC 815 requires each contract that is not a derivative in its entirety be assessed to determine whether it contains embedded derivatives that are required to be bifurcated and accounted for as a derivative financial instrument. The embedded derivative is bifurcated from the host contract and accounted for as a freestanding derivative if the combined instrument is not accounted for in its entirety at fair value with changes in fair value recorded in earnings, the terms of the embedded derivative are not clearly and closely related to the economic characteristics of the host contract, and a separate instrument with the same terms as the embedded derivative would qualify as a derivative instrument. Embedded derivatives are measured at fair value and remeasured at each subsequent reporting period, and recorded within convertible notes, net on the accompanying condensed consolidated balance sheets and changes in fair value recorded in other expense within the condensed consolidated statements of operations. Debt discounts under these arrangements are amortized to interest expense using the interest method over the earlier of the term of the related debt or their earliest date of redemption.

The Company has analyzed the redemption, conversion, settlement, and other derivative instrument features of its Convertible Notes.

- The Company identified that the (i) redemption features, (ii) lender’s optional conversion feature, (iii) lender’s optional conversion upon merger event feature and (iv) additional interest rate upon certain events feature meet the definition of a derivative. The Company analyzed the scope exception for all the above features under ASC 815-10-15-74(a).

[Table of Contents](#)

- Based on the further analysis, the Company identified that the (i) lender's optional conversion feature, (ii) lender's optional conversion upon merger event feature and (iii) additional interest rate upon certain events feature, do not meet the settlement criteria to be considered indexed to equity. The Company concluded that each of these features should be classified as a derivative liability measured at fair value with the changes in fair value in the condensed consolidated statement of operations.
- The Company also identified that the redemption features are settled in cash and do not meet the indexed to equity and the equity classification scope exception, thus, they must be bifurcated from the Convertible Notes and accounted for separately at fair value on a recurring basis reflecting the changes in fair value in the condensed consolidated statement of operations.

The Company determined the Convertible Notes contained multiple embedded derivatives that are required to be bifurcated, two of which are conversion features.

As per ASC 815, the fair value election is allowable provided the debt was not issued at a substantial premium. The Company concluded that the Convertible Notes were not issued at a premium and hence the Company elected the fair value option under ASC 815-15-25. The Company elected to record changes in fair value through the condensed consolidated statement of operations as a fair value adjustment of the convertible debt each reporting period (with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable). The Company has elected to separately present interest expense related to the Convertible Notes within the condensed consolidated statement of operations. Thus, the multiple embedded derivatives do not need to be separately bifurcated and fair valued. The Convertible Notes are reflected at their respective fair values on the condensed consolidated balance sheets.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, par value \$0.0001 ("Common Stock"), among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and then remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the liability classified warrants are recognized as other income or expense on the condensed consolidated statements of operations.

Revenue Recognition

The Company creates customized precision milled intraoral devices. When devices are sold, they include an assurance-type warranty guaranteeing the fit and finish of the product for a period of 3 years from the date of sale.

The Company recognizes revenue upon meeting the following criteria:

- Identifying the contract with a customer: customers submit authorized prescriptions and oral impressions to the Company. Authorized prescriptions constitute the contract with customers.
- Identifying the performance obligations within the contract: The sole performance obligation is the shipment of a completed customized intraoral device.
- Determining the transaction price: Prices are determined by standardized pricing sheets and adjusted for estimated returns, discounts, and allowances.

- Allocating the transaction price to the performance obligations: The full transaction price is allocated to the shipment of the completed intraoral device as it is the only element in the transaction.
- Recognizing revenue as the performance obligation is satisfied at a point in time: revenue is recognized upon transfer of control which occurs upon shipment of the product.

The Company does not require collateral or any other form of security from customers. Inbound shipping and handling costs related to sales are billed to customers. We charge for inbound shipping/handling and the costs are classified as Cost of Revenue. Outbound shipping costs are not billed to customers and are included in sales and marketing expenses. Taxes collected from customers and remitted to governmental authorities are excluded from revenue.

Standalone selling price for the various intraoral device models are determined using the Company's standard pricing sheet. The Company invoices customers upon shipment of the product and invoices are due within 30 days. Amounts that have been invoiced are recorded in accounts receivable and revenue as all revenue recognition criteria have been met. Given the nominal value of each transaction, the Company does not offer a financing component related to its revenue arrangements.

Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. Generally, the Company determines that a lease exists when (1) the contract involves the use of a distinct identified asset, (2) the Company obtains the right to substantially all economic benefits from use of the asset, and (3) the Company has the right to direct the use of the asset. A lease is classified as a finance lease when one or more of the following criteria are met: (1) the lease transfers ownership of the asset by the end of the lease term, (2) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (3) the lease term is for a major part of the remaining useful life of the asset, (4) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset or (5) the asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease is classified as an operating lease if it does not meet any of these criteria.

At the lease commencement date, the Company recognizes a right-of-use asset and a lease liability for all leases, except short term leases with an original term of twelve months or less. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, less any lease incentives received. All right-of-use assets are periodically reviewed for impairment in accordance with standards that apply to long-lived assets. The lease liability is initially measured at the present value of the lease payments, discounted using an estimate of the Company's incremental borrowing rate for a collateralized loan with the same term as the underlying leases for operating leases and the implied rate in the lease agreement for finance leases.

Lease payments included in the measurement of lease liabilities consist of (1) fixed lease payments for the noncancelable lease term, (2) fixed lease payments for optional renewal periods where it is reasonably certain the renewal option will be exercised, and (3) variable lease payments that depend on an underlying index or rate, based on the index or rate in effect at lease commencement. The Company's real estate operating lease agreement requires variable lease payments that do not depend on an underlying index or rate established at lease commencement. Such payments and changes in payments are recognized in operating expenses when incurred.

Lease expense for operating leases consists of the fixed lease payments recognized on a straight-line basis over the lease term plus variable lease payments as incurred. Lease expense for finance leases consists of the amortization of assets obtained under finance leases on a straight-line basis over the lease term and interest expense on the lease liability based on the discount rate at lease commencement.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to Common Stockholders is calculated by dividing the net loss attributable to Common Stockholders by the weighted average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share attributable to Common Stockholders is the same as basic net loss per share attributable to Common Stockholders, since the effects of potentially dilutive securities are antidilutive.

Reclassifications

Certain prior year balances have been reclassified in order to conform to the current period presentation. These reclassifications have no impact on previously reported earnings or cash flows.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 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*, to clarify the accounting for certain financial instruments with characteristics of liabilities and equity. The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock by removing the cash conversion model and the beneficial conversion feature model. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in-capital. In addition, this ASU improves disclosure requirements for convertible instruments and earnings-per-share guidance. The ASU also revises the derivative scope exception guidance to reduce form-over-substance-based accounting conclusions driven by remote contingent events. The Company early adopted ASU 2020-06 effective January 1, 2023, which eliminated the need to assess whether a beneficial conversion feature needs to be recognized upon the issuance of new convertible instruments.

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe any accounting pronouncements issued through the date of this report will have a material impact on the Company's consolidated financial statements.

NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	September 30, 2023	December 31, 2022
Manufacturing equipment	\$ 3,626,396	\$ 2,516,859
Computers and software	1,621,474	1,608,075
Leasehold improvements	822,134	441,956
Furniture	—	27,587
	6,070,004	4,594,477
Less accumulated depreciation and amortization	(2,330,383)	(2,190,075)
Property and equipment, net	<u>\$ 3,739,621</u>	<u>\$ 2,404,402</u>

Depreciation and amortization expense for property and equipment was \$0.4 million and \$0.2 million for the three months ended September 30, 2023 and 2022, respectively, and \$0.6 million and \$0.3 million for the nine months ended September 30, 2023 and 2022, respectively.

During the nine months ended September 30, 2023, the Company disposed of property and equipment of \$0.7 million which had an accumulated depreciation and amortization balance of \$0.6 million. The resulting \$0.1 million loss on disposal is reflected in the condensed consolidated statement of operations as other expense.

NOTE 4 — INVENTORY

Inventory consists of the following:

	September 30, 2023	December 31, 2022
Raw materials	\$ 1,509,768	\$ 561,726
Work-in-process	140,329	78,219
	<u>\$ 1,650,097</u>	<u>\$ 639,945</u>

The Company did not have any excess or obsolete inventory reserves at September 30, 2023 and December 31, 2022.

NOTE 5 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022
Compensation related accruals	\$ 3,274,248	\$ 2,104,008
Marketing programs	940,930	611,642
Interest	381,595	110,239
Warranty	464,812	269,496
Professional fees	1,873,278	129,169
Inventory purchases and freight	1,242,311	—
Other	196,308	481,540
	<u>\$ 8,373,482</u>	<u>\$ 3,706,094</u>

NOTE 6 — LEASES

The Company's previous corporate office lease had a remaining term of approximately one year as of December 31, 2022. On February 28, 2023, the Company abandoned the previous corporate office premises. There is no new cash inflow generated or expected from the sale or sublease of property and leasehold improvements at the location. The Company recorded an impairment loss of \$0.2 million on the right of use ("ROU") operating lease assets and accrued liabilities of \$0.1 million in anticipation of expected common area maintenance payments on the lease through December 31, 2023. The impairment loss and the accrued expenses are reflected as other expense in the condensed consolidated statements of operations for the three and nine months ended September 30, 2023.

On May 17, 2022, the Company signed a ten-year lease for the Company's new corporate headquarters. The lease commenced on December 15, 2022. The monthly payment is approximately \$0.1 million and is subject to stated annual escalations. The Company received five months of free rent.

The Company's finance leases consist of various machinery, equipment, computer-related equipment, or software and have remaining terms from less than one year to five years.

The components of the Company's lease cost, weighted average lease terms and discount rates are presented in the tables below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Lease Cost:				
Operating lease cost	\$ 223,304	\$ 68,709	\$ 711,661	\$ 206,126
Finance lease cost:				
Amortization of assets obtained under finance leases	\$ 285,251	\$ 274,712	\$ 681,763	\$ 597,904
Interest on lease liabilities	126,880	104,409	282,990	223,263
	<u>\$ 412,131</u>	<u>\$ 379,121</u>	<u>\$ 964,753</u>	<u>\$ 821,167</u>

Lease term and discount rate As of September 30, 2023	Weighted average discount rate:	Weighted average remaining lease term:
Operating leases	10.0 %	9.3 years
Finance leases	10.2 %	3.2 years

	Nine Months Ended September 30, 2023
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 355,060
Operating cash flows from finance leases	246,879
Financing cash flows from finance leases	1,026,701

Right-of-use assets consisted of the following as of September 30, 2023:

	Total
Manufacturing equipment	\$ 5,237,167
Computers and software	700,234
Leasehold improvements	218,244
Total	6,155,645
Less accumulated amortization	(2,623,405)
Right-of-use assets for finance leases	3,532,240
Right-of-use assets for operating leases	5,154,399
Total right-of-use assets	<u>\$ 8,686,639</u>

At September 30, 2023, the following table presents maturities of the Company's finance lease liabilities:

Nine months ended September 30, 2023	Total
2023 (remaining three months)	\$ 576,315
2024	1,287,461
2025	1,057,500
2026	739,115
2027	192,568
Thereafter	47,300
Total minimum lease payments	3,900,259
Less amount representing interest	(563,452)
Present value of minimum lease payments	3,336,807
Less current portion	(1,109,899)
Finance lease obligations, less current portion	<u>\$ 2,226,908</u>

At September 30, 2023, the following table presents maturities of the Company's operating lease liabilities:

Nine months ended September 30, 2023	Total
2023 (remaining three months)	\$ 379,887
2024	842,553
2025	867,831
2026	893,862
2027	920,679
Thereafter	4,761,873
Total minimum lease payments	8,666,685
Less: amount representing interest	(3,107,847)
Present value of minimum lease payments	5,558,838
Less: current portion	(290,869)
Operating lease liabilities, less current portion	\$ 5,267,969

NOTE 7 — DEBT

Equipment Financing Obligation

The Company's future principal maturities under the equipment financing obligation are summarized as follows:

At September 30, 2023	Total
2023 (remaining three months)	\$ 13,363
2024	56,995
2025	63,698
2026	64,952
Total principal maturities	199,008
Less: current portion	(55,510)
Equipment financing obligation, net of current portion	\$ 143,498

Subordinated Notes

The Company received advances under subordinated promissory note agreements for total proceeds of \$0.4 million during the nine months ended September 30, 2022. No issuance costs were incurred.

Bridge Loans (Unsecured Subordinated Promissory Notes)

During the nine months ended September 30, 2022, the Company received proceeds of \$5.1 million from unsecured subordinated promissory notes (the "Bridge Loans"). Prior to the closing of our December 2022 merger (the "Business Combination"), the Bridge Loans were converted into Series A Redeemable Convertible Preferred Stock.

During March 2022, \$0.5 million of the Bridge Loans were repaid. The primary stockholder of the Company was the borrower on this Bridge Loan, and a representative of this primary stockholder is a member of the Company's board of directors ("Board of Directors").

Convertible Debt Agreements

Senior Convertible Notes

On December 6, 2022, the Company entered into the Indenture for Senior Secured Convertible Notes due December 6, 2025, dated December 6, 2022 by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (as amended, the “Senior Indenture”), and issued Senior Secured Convertible Notes, due December 6, 2025 (the “Existing Senior Convertible Notes”), with an aggregate principal amount of \$16.96 million, pursuant to the senior securities purchase agreement, dated August 26, 2022. In connection with the closing of the offering of the Existing Senior Convertible Notes, the Company issued 36,469 shares of Common Stock and 169,597 warrants (the “Existing Senior Convertible Notes Warrants”) to purchase Common Stock. The Existing Senior Convertible Notes Warrants entitle the note holders to purchase shares of Common Stock, subject to adjustment, at a purchase price per share of \$11.50. The debt bears interest at 9% per annum. Interest is payable in cash quarterly.

On June 29, 2023, the Company entered into the [First Supplemental Indenture, dated as of June 29, 2023, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association](#) (the “First Senior Supplemental Indenture”). The First Senior Supplemental Indenture, among other things, (i) effects certain changes to the minimum EBITDA and minimum revenue financial covenants (ii) requires mandatory redemption of the Existing Senior Convertible Notes in consecutive quarterly installments equal to \$847,990 in the aggregate on January 1, April 1, July 1 and October 1 of each year, commencing October 1, 2024, until the earlier of the maturity date of the Existing Senior Convertible Notes or the date the Existing Senior Convertible Notes are no longer outstanding, and (iii) corrects an error in the definition of Conversion Rate.

On September 20, 2023, the Company entered into the Second Supplemental Indenture (the “Second Senior Supplemental Indenture”) to the Senior Indenture, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent. The Second Senior Supplemental Indenture amends the Senior Indenture to, among other things, permit the sale of the securities underlying the convertible debt (the “Securities”) and the Exchanges.

Subordinated Convertible Notes

On December 6, 2022, the Company entered into that certain Indenture for Subordinated Secured Convertible Notes due April 6, 2026, dated December 6, 2022 by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (as amended, the “Subordinated Indenture”), and issued the Subordinated Secured Convertible Notes due April 6, 2026 (“Existing Subordinated Convertible Notes” and, together with the Existing Senior Convertible Notes, the “Existing Convertible Notes”), with an aggregate principal amount of approximately \$17.45 million, pursuant to the previously disclosed Subordinated Securities Purchase Agreement, dated August 26, 2022. In connection with the closing of the offering, the Company issued 290,244 shares of Common Stock and 1,745,310 warrants (“Subordinated Convertible Notes Warrants” and, together with the Senior Convertible Notes Warrants, the “Convertible Notes Warrants”) to purchase Common Stock to certain Convertible Debt holders. The debt has an interest rate of Prime Rate plus an additional 9% per annum with a term of 3 years. Interest is due quarterly in cash or in kind at the option of the Company.

On June 29, 2023, the Company entered into the [First Supplemental Indenture, dated as of June 29, 2023, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association](#) (the “First Subordinated Supplemental Indenture”), which, among other things, (i) effects certain changes to the minimum EBITDA and minimum revenue financial covenants and (ii) corrects an error in the definition of Conversion Rate.

On September 8, 2023, the Company issued 192,381 shares of Common Stock in connection with a notice of conversion from a holder of the Company’s Subordinated Convertible Notes, pursuant to which such holder irrevocably exercised its right to convert \$1,000,000 principal amount. The Company recorded the fair value of the principal amount and accrued interest converted of \$0.9 million as Common Stock and additional paid-in capital.

On September 20, 2023, the Company entered into the Second Supplemental Indenture (the “Second Subordinated Supplemental Indenture”) to the Subordinated Indenture, pursuant to which the Company issued the Existing Subordinated Convertible Notes. The

Second Subordinated Supplemental Indenture amends the Subordinated Indenture to, among other things, permit the sale of the Securities and the Exchanges.

Financing Transaction

On September 20, 2023, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”, and the transactions contemplated by the Securities Purchase Agreement, the “Financing Transaction”) with certain third-party and related party investors (the “Investors”), pursuant to which the Company issued (i) an aggregate of 10,426 shares of the Company’s Series A Preferred Stock, par value \$0.0001 per share (the “Series A Preferred Stock”), for an aggregate purchase price of \$10.4 million at a per share purchase price of \$1,000, and (ii) (A) with respect to Investors that held the Existing Convertible Notes, new convertible notes on substantially similar terms to such Noteholder Investor’s Existing Convertible Notes other than that such new notes will be convertible into shares of Common Stock, at a conversion price of \$1.00 per share subject to the terms and conditions of the applicable new indenture pursuant to which the applicable series of New Notes have been issued by the Company (the “New Notes”), in exchange for such Noteholder Investor’s portion of the principal amount outstanding of the Existing Notes (the “Exchanges”) pursuant to exchange agreements entered into between the Company and each of the Noteholder Investors (together, the “Exchange Agreements”) and/or (B) warrants to purchase shares of Common Stock at an exercise price of \$1.00 per share (such warrants, the “Transaction Warrants”).

The Investors include certain members of the Company’s Board of Directors and certain executive officers of the Company, as well as affiliates and investment vehicles for such persons that held the Company’s Existing Convertible Notes. Convertible Noteholders representing approximately \$3.4 million in principal amount of the Senior Convertible Notes and approximately \$12.1 million in principal amount of the Subordinated Convertible Notes participated in the Financing Transaction.

The Financing Transaction closed on multiple dates: September 20, 2023, September 26, 2023, and October 20, 2023. The exchange of the Existing Convertible Notes, including the entrance into the indentures governing the New Notes, occurred on October 11, 2023.

In such Exchanges, the Noteholder Investors received principal amount in the new notes equal to up to 300% of the purchase price paid by such Noteholder Investor to purchase its Series A Preferred Stock. Any proceeds in excess of such amount results in the Noteholder Investors purchasing Transaction Warrants.

As a result of the Financing Transaction, in September 2023, the Noteholder Investors effectively contributed an aggregate of \$6.4 million of cash to the Company in exchange for 6,376 shares of Series A Preferred Stock, Transaction Warrants exercisable into an aggregate of 1,404,524 shares of Common Stock, and the repricing of the conversion feature of their Convertible Notes, while the other Investors contributed an aggregate of \$3.2 million of cash to the Company in exchange for 3,150 shares of Series A Preferred Stock and Transaction Warrants exercisable into an aggregate of 3,150,000 shares of Common Stock.

Although exchange of the Convertible Notes did not occur until October 11, 2023, the Company determined that from a legal and accounting standpoint, the debt was modified in September 2023 based on the SPA terms and the receipt of the cash proceeds in connection with the first closing. Prior to the Financing Transaction, the Senior Convertible Notes and Subordinated Convertible Notes had conversion rates of \$5.50 and \$5.20 per share, respectively. The repricing of the Convertible Notes to \$1.00 per share made the conversion features of the Convertible Notes substantive again based on the Company’s stock price as of the Initial Closing.

Pursuant to the terms of the Securities Purchase Agreement and the Transaction Warrants, until approval is obtained from the Company’s stockholders, the following limitations apply:

- The Series A Preferred Stock cannot be converted into more than 19.95% of the number of shares of Common Stock outstanding as of the date of the SPA;
- The Transaction Warrants are not exercisable;
- The Series A Preferred Stock held by directors and officers of the Company is not convertible into Common Stock; and
- The New Notes are not convertible at the reduced \$1.00 conversion rate.

As a condition to the Initial Closing, the Company was required to secure contractual commitments to support the Financing Transaction from greater than 50% of stockholders. The Company secured support from stockholders representing 51.2% of the Common Stock then outstanding.

The Company assessed the accounting for the Financing Transaction with the Noteholder Investors and concluded that it does not meet the criteria for a troubled debt restructuring or an induced conversion. The Company next considered if the transaction represents a debt modification or extinguishment and concluded the transaction represents a debt extinguishment in accordance with ASC paragraph 470-50-40-10 as both of the following circumstances apply:

- a. The transaction resulted in a modification of an embedded conversion option, from which the change in the fair value of the embedded conversion option (calculated as the difference between the fair value of the embedded conversion option immediately before and after the modification or exchange) is at least 10 percent of the carrying amount of the original debt instrument immediately before the modification or exchange.
- b. The transaction resulted in a modification or an exchange of debt instruments that adds a substantive conversion option.

Accordingly, the Company accounted for the transaction as an extinguishment of the original debt and the recognition of new debt, which is initially measured at its fair value. The fair value of the new debt is used to determine the debt extinguishment gain or loss to be recognized. The Company assessed the classification of the Transaction Warrants issued in connection with the Financing Transaction and determined that the Transaction Warrants are equity classified. As discussed in Note 9, the Company determined that the Series A Preferred Stock is mezzanine classified and therefore should be initially recognized at fair value.

The following table summarizes the computation of the loss on debt extinguishment recognized during the three months ended September 30, 2023:

	Amount
Fair value - Senior Convertible Notes (pre-financing)	\$ 2,456,607
Fair value - Subordinated Convertible Notes (pre-financing)	7,616,902
	10,073,509
<u>Less consideration transferred to Noteholder Investors:</u>	
Fees paid to Noteholder Investors	(62,620)
Fair value of Series A Preferred Stock	(7,807,681)
Fair value of warrants	(787,250)
Fair value of Senior Convertible Notes (post-financing)	(3,599,388)
Fair value of Subordinated Convertible Notes (post-financing)	(13,935,613)
	(26,192,552)
<u>Plus consideration received from Noteholder Investors:</u>	
Cash	6,376,000
Loss on Debt Extinguishment:	<u>(\$ 9,743,043)</u>

The fair values of the Series A Preferred Stock and Transaction Warrants were determined using the assistance of a third-party valuation specialist and include Level 3 fair value inputs. The significant assumptions used related to the Series A Preferred Stock include a risky yield (risk-adjusted discount rate) of 42.0%, volatility rate of 65.0%, risk free rate of 5.0%, and an estimated exit date of April 2026. The assumptions used related to the Transaction Warrants include an asset price of \$0.97, volatility rate of 65.0%, risk free rate of 4.5%, no dividends, and an expected term of 5.0 years.

In respect to the non-Noteholder Investors, the fair value of the consideration transferred was also determined to be greater than the proceeds received. The Company determined that based on the participation level by third-party investors, the transaction does not represent a deemed dividend. As such, the Company recognized a financing loss of \$2.5 million which is included in other expense in the consolidated statements of operations. The financing loss is computed as follows:

Cash proceeds received	\$ 3,150,000
Less: fair value of Series A Preferred Stock	(3,857,308)
Less: fair value of warrants	(1,765,607)
Other financing expense	<u>(\$ 2,472,915)</u>

The Company incurred \$1.5 million of legal and other transaction related costs, of which approximately \$0.1 million were deemed to be lender costs and included in the computation of the loss on debt extinguishment. The remaining transaction costs were expensed as other expense in the consolidated statements of operations.

Fair Value Election

The Company has elected to measure the Convertible Notes, including the New Notes, in their entirety at fair value with changes in fair value recognized as non-operating gain or loss in the consolidated statements of operations (with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable).

The estimated fair values of the convertible debt were determined using a Monte Carlo Simulation method. We simulated the stock price using a Geometric Brownian Motion until maturity. For each simulation path we calculated the convertible bond value at maturity and then discount that back to the valuation date. The following assumptions were used as of September 30, 2023 and December 31, 2022:

	Monte Carlo Simulation Assumptions			
	Asset Price	Risky Yield	Expected Volatility	Risk-Free Interest Rate
As of September 30, 2023				
Senior Convertible Notes	\$ 1.04	26.70 %	60 %	4.99 %
Subordinated Convertible Notes	1.04	36.10 %	60 %	4.91 %

	Monte Carlo Simulation Assumptions			
	Asset Price	Risky Yield	Expected Volatility	Risk-Free Interest Rate
As of December 31, 2022				
Senior Convertible Notes	\$ 5.56	31.80 %	45 %	4.23 %
Subordinated Convertible Notes	5.56	41.20 %	45 %	4.19 %

The following is a summary of changes in fair value of the Convertible Notes for three and nine months ended September 30, 2023:

	Senior Convertible Notes	Subordinated Convertible Notes
Beginning fair value, January 1, 2023	\$ 13,651,000	\$ 10,355,681
Paid-in-kind interest	—	723,699
Change in fair value of debt	827,000	1,000,000
Fair value as of March 31, 2023	14,478,000	12,079,380
Paid-in-kind interest	—	793,594
Change in fair value of debt	(1,549,596)	2,352,026
Fair value as of June 30, 2023	12,928,404	15,225,000
Paid-in-kind interest	—	1,010,814
Conversion of Subordinated Convertible Notes to Common Stock	—	(919,568)
Increase in fair value of debt in connection with debt extinguishment transaction	1,142,781	6,318,711
Change in fair value of debt	(784,780)	(2,914,956)
Ending fair value, September 30, 2023	\$ 13,286,405	\$ 18,720,000

The Convertible Notes are subject to a minimum revenue, cash, and EBITDA financial covenants. Management believes that the Company is in compliance with all financial covenants as of September 30, 2023. From July 1, 2023, the Convertible Notes require the Company to maintain a minimum cash balance of \$4.5 million on the first of each calendar month.

NOTE 8 – COMMON STOCK WARRANTS

Estimated Fair Value of Outstanding Warrants Classified as Liabilities

The estimated fair value of outstanding warrants classified as liabilities is determined at each consolidated balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recently reported balance sheet date is recorded in the consolidated statements of operations as a change in fair value of warrant liability.

The fair value of the outstanding warrants accounted for as liabilities as of September 30, 2023 and December 31, 2022 use Level 3 inputs and are calculated using the Black-Scholes option pricing model with the following assumptions:

As of September 30, 2023	Exercise Price	Asset Price	Dividend Yield	Expected Volatility	Risk-Free Interest Rate	Expected Life
Convertible Notes Warrants	\$ 11.50	\$ 1.04	0 %	65 %	4.70 %	4.18 years
As of December 31, 2022	Exercise Price	Asset Price	Dividend Yield	Expected Volatility	Risk-Free Interest Rate	Expected Life
Convertible Notes Warrants	\$ 11.50	\$ 5.56	0 %	40 %	4.00 %	4.93 years

The changes in fair value of the outstanding warrants classified as liabilities for the three and nine months ended September 30, 2023 are as follows:

	Convertible Notes Warrants
Warrant liability, January 1, 2023	\$ 1,991,503
Change in fair value	842,559
Warrant liability, March 31, 2023	2,834,062
Change in fair value	(2,106,398)
Warrant liability, June 30, 2023	727,664
Change in fair value	(593,621)
Warrant liability, September 30, 2023	\$ 134,043

As of September 30, 2023 and December 31, 2022, there were 9,151,704 and 4,597,180 equity classified warrants outstanding, respectively.

NOTE 9 – REDEEMABLE CONVERTIBLE PREFERRED STOCK

Our Board of Directors has designated 25,000 shares of preferred stock as Series A Preferred Stock. The Series A Preferred Stock has no maturity and is not subject to any sinking fund or redemption and will remain outstanding indefinitely unless and until converted by the holder or the Company redeems or otherwise repurchases the Series A Preferred Stock.

In September 2023, the Company issued 9,526 shares of Series A Preferred Stock and the corresponding Transaction Warrants to the Investors (see Note 7) in exchange for total cash proceeds of \$9.5 million. In October 2023, the Company issued 900 shares of Series A Preferred Stock and the corresponding Transaction Warrants in exchange for total cash proceeds of \$0.9 million.

Dividends

Dividends on each share of Series A Preferred Stock are payable at the rate of 8% (the “Dividend Rate”) of the purchase price of \$1,000.00 per share (the “Stated Value”). Dividends are payable semi-annually to holders of record on March 1 and September 1 on March 15 and September 15 of each year, respectively, with the first payment date being March 15, 2024, the dividend for which will reflect the period from closing through March 15, 2024.

Dividends are payable in shares of Common Stock (a “PIK Dividend”). The number of dividend shares is equal to the Stated Value of each such share of Series A Preferred Stock multiplied by the dividend rate of 8.0% per annum and divided by \$1.00, as adjusted

from time to time for any stock split, stock dividend, recapitalization or otherwise, computed on the basis of a 360-day year and twelve 30-day months. Any fractional shares of a PIK Dividend will be rounded to the nearest whole share. All shares of Common Stock issued in payment of a PIK Dividend will be duly authorized, validly issued, fully paid and non-assessable. Dividends will accumulate whether or not the Company has earnings, there are funds legally available for the payment of those dividends and whether or not those dividends are declared by the Company's Board of Directors.

Conversion Features

Each share of Series A Preferred Stock is convertible at any time and in the sole discretion of the holder, into shares of Common Stock at a conversion rate of \$1.00 per share (the "Conversion Rate") plus any accrued but unissued PIK Dividends, when converted, subject to certain restrictions on conversion prior to the Company obtaining stockholder approval. If the Company issues or sells Common Stock at a price below the current conversion rate of \$1.00 per share, the conversion rate will be adjusted downward immediately following the dilutive issuance. The new conversion rate will be calculated based on a formula that takes into account the previous conversion rate, number of shares outstanding before and after issuance, and the consideration received by the Company in connection with the dilutive issuance. Certain types of agreements to sell Common Stock at market pricing will be evaluated on a quarterly basis or immediately prior to a Liquidation Event for purposes of determining if they collectively constitute a dilutive issuance.

Following receipt of the stockholder approval, the Company can initiate a mandatory conversion at any time when the resale of issued Common Stock is covered under an effective registration statement or can be sold without volume limitations under Rule 144 (or successor rule), as determined by the counsel to the Company. The Series A Preferred Stock will automatically convert into shares of Common Stock at the Conversion Rate, as follows: (i) 50% of the issued and outstanding Series A Preferred Stock will convert into shares of Common Stock if the Volume-weighted average price (VWAP) trading price for the shares of Common Stock are trading on a national exchange is greater than \$4.50 per share for twenty of any thirty consecutive trading days, and (ii) the remaining issued and outstanding Series A Preferred Stock will convert into shares of Common Stock if the VWAP trading price for the shares of Common Stock are trading on a national exchange greater than \$6.00 per share for twenty of any thirty consecutive trading days.

The Company analyzed the embedded conversion options for derivative accounting consideration under ASC 815-15 "Derivatives and Hedging" and determined that the conversion options are equity classified.

The Company is restricted from issuing shares of Common Stock exceeding 19.95% of the outstanding Common Stock (the "Exchange Cap"), unless approved by the Company's stockholders, with each holder of Series A Preferred Stock only able to convert their proportional percentage of the shares allowable under the Exchange Cap. The Company is required to call a meeting of stockholders within 90 days of the Initial Closing to vote on the issuance of shares above the Exchange Cap.

Voting Rights

Each Series A Preferred Stockholder is entitled to the whole number of votes equal to the number of shares of Common Stock into which such holder's Series A Preferred Stock would be convertible on the record date for the vote or consent of stockholders at a conversion price of \$1.04 per share of Common Stock rounded to the nearest whole share.

Liquidation Preferences and Redemption Rights

The Series A Preferred Stock has senior ranking over Common Stock of the Company, and junior to the Company's indebtedness, in each case for purposes of dividends, distributions, and payments in a liquidation event.

In the event of a liquidation event, holders of Series A Preferred Stock are entitled to receive in cash out of the assets of the Company legally available, whether from capital or from earnings available for distribution to its stockholders, before any amount shall be paid to the holders of Common Stock, an amount in cash per share of Series A Preferred Stock equal to the greater of: (i) 150% of the Stated Value and (ii) the value of the per share consideration paid to the holders of the Common Stock in the Liquidation Event as if the Series A Preferred Stock held by such holder had been converted prior to the liquidation event, subject to certain exceptions as stipulated in the Company's Certificate of Designations for the Series A Preferred Stock.

The Series A Preferred Stock are redeemable upon the occurrence of any transaction or series of related transactions pursuant to which the Company effects (i) any merger or consolidation of the Company where the Company is not the surviving entity, (ii) any sale

of all or substantially all of its assets, or (iii) any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (a “Fundamental Transaction”). In the event of a Fundamental Transaction, holders of Series A Preferred Stock are entitled to receive in cash the greatest of: (i) 150% of the Stated Value, (ii) the Stated Value of Series A Preferred Stock, plus to the extent holders of Common Stock will receive cash consideration in exchange for their Common Stock in a Fundamental Transaction, cash consideration equal to the value of any accrued but unpaid dividends, and (iii) the value of the per share consideration paid to the holders of the Common Stock in the Fundamental Transaction as if the Series A Preferred Stock held by such holder had been converted prior to the Fundamental Transaction.

As part of the Company’s analysis of the classification of the Series A Preferred Stock, the Company considered the guidance in ASC 480-10-S99-3A and in particular paragraphs 2 and 3f, which require preferred securities that are redeemable for cash or other assets to be classified outside of permanent equity if they are redeemable upon the occurrence of an event that is not solely within the control of the issuer. Due to the consideration payable upon a Fundamental Transaction and the liquidation preferences of the Series A Preferred Stock providing for payout on the Series A Preferred Stock prior to payment to the Common Stockholders, the Company cannot avail itself of the limited exception of paragraph ASC 480-10-S99-3A-3f. As a result, the Company concluded that the Series A Preferred Stock are subject to ASR 268, Presentation in Financial Statements of “Redeemable Preferred Stocks,” and should be classified outside of permanent equity.

NOTE 10 – COMMON STOCK

The Company has reserved shares of Common Stock for the following as of September 30, 2023:

2022 Equity Incentive Plan reserve	2,411,283
Reserve for earn-out shares	3,000,000
Reserve for exercise of warrants	12,014,300
Reserve for convertible debt	18,945,919
Employee stock purchase plan	500,000
Total	<u>36,871,502</u>

NOTE 11 - EARN-OUT SHARES

In connection with the Business Combination, certain of the Company’s original stockholders are entitled to receive up to 3,000,000 Earn-out shares in three tranches:

- (1) the first tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of the Company’s Common Stock is \$12.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing;
- (2) the second tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of the Company’s Common Stock is \$15.00 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing; and
- (3) the third tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of the Company’s Common Stock is \$17.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing.

The Earn-out shares will be allocated among the Company’s stockholders in proportion to the number of shares issued to them at the closing that continue to be held by them.

Due to the variability in the number of Earn-out shares at settlement which could change upon a control event, the Earn-out arrangement contains a settlement provision that violates the indexation guidance under ASC 815-40 and liability classification is required. The Company recorded the earnout liability initially at fair value, and subsequently remeasures the liability with changes in fair value recorded in the consolidated statement of operations at each reporting period.

The changes in fair value of the earnout liability for the three and nine months ended September 30, 2023 are as follows:

	Earnout Liability
Earnout liability, January 1, 2023	\$ 12,810,000
Change in fair value	(1,500,000)
Earnout liability, March 31, 2023	11,310,000
Change in fair value	(6,700,000)
Earnout liability, June 30, 2023	4,610,000
Change in fair value	(3,880,000)
Earnout liability, September 30, 2023	\$ 730,000

NOTE 12 — STOCK-BASED COMPENSATION

During May 2023, the Company issued 20,000 shares of Common Stock to a consultant for services received. The fair value of the shares issued of \$0.2 million was recognized as a selling, general and administrative expense with a corresponding credit to additional paid-in capital.

As of September 30, 2023, the Company has 339,000 shares of Common Stock in escrow for any merger consideration adjustments which are expected to be released from escrow within twelve months from the date of the Business Combination.

2022 Equity Incentive Plan

During the nine months ended September 30, 2023, the Company granted 1,478,915 options under the 2022 Equity Incentive plan to certain employees and consultants of the Company.

Stock option activity for the nine months ended September 30, 2023 was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2023	—	\$ —		
Granted	1,478,915	5.20		
Exercised	—	—		
Cancelled	(98,232)	5.20		
Outstanding at September 30, 2023	1,380,683	\$ 5.20	9.34 years	\$ —
Exercisable at September 30, 2023	—	—	—	—
Vested and expected to vest as of September 30, 2023	1,380,683	\$ 5.20	9.34 years	\$ —

As of September 30, 2023, and December 31, 2022, there were no exercisable or vested options.

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2023 was \$2.91. The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of the stock options was estimated using the following weighted average assumptions:

	Nine Months Ended September 30, 2023
Dividend yield	0.0%
Expected volatility	55.0%
Risk-free interest rate	3.6%
Expected life	6.2 years

Dividend Rate—The expected dividend rate was assumed to be zero, as the Company had not previously paid dividends on Common Stock and has no current plans to do so.

Expected Volatility—The expected volatility was derived from the historical stock volatilities of several public companies within the Company’s industry that the Company considers to be comparable to the business over a period equivalent to the expected term of the stock option grants.

Risk-Free Interest Rate—The risk-free interest rate is based on the interest yield in effect at the date of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the option’s expected term.

Expected Term—The expected term represents the period that the Company’s stock options are expected to be outstanding. The expected term of option grants that are considered to be “plain vanilla” are determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For other option grants not considered to be “plain vanilla,” the Company determined the expected term to be the contractual life of the options.

Forfeiture Rate—The Company recognizes forfeitures as they occur.

The Company has recorded stock-based compensation expense for the three and nine months ended September 30, 2023 related to the grants of stock option awards to employees and nonemployees in the condensed consolidated statement of operations as follows:

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Cost of revenue	\$ 4,478	\$ 11,940
Sales and marketing	21,158	87,324
Research and development	52,453	164,260
General and administrative	68,507	452,669
	\$ 146,596	\$ 716,193

As of September 30, 2023, unamortized compensation expense related to unvested stock options was \$3.3 million, which is expected to be recognized over a weighted average period of 3.3 years.

2023 Employee Stock Purchase Plan

The Company’s Board of Directors previously adopted, and the Company’s stockholders approved, the Company’s 2023 Employee Stock Purchase Plan (the “2023 ESPP”).

The 2023 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of shares of the Company’s Common Stock at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 500,000 shares of Common Stock were available for purchase at adoption of the 2023 ESPP. The first offering period under the plan commenced on June 15, 2023. There were no shares issued under the plan for the nine months ended September 30, 2023. As of September 30, 2023, 500,000 shares of Common Stock remained available for issuance under the 2023 ESPP.

The Company estimates the fair value of ESPP grants on their grant date using the Black-Scholes option pricing model. The estimated fair value of ESPP grants is amortized on a straight-line basis over the requisite service period of the grants. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP grants. ESPP compensation expense for the nine months ended September 30, 2023 was de minimis.

NOTE 13 — NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of the basic and diluted net loss per share attributable to Common Stockholders for the three and nine months ended September 30, 2023:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Numerator:				
Net loss attributable to Common Stockholders	\$ (11,238,803)	\$ (3,548,962)	\$ (17,226,044)	\$ (9,353,340)
Denominator:				
Weighted-average common shares outstanding	<u>16,115,254</u>	<u>24,713,218</u>	<u>16,071,719</u>	<u>24,611,666</u>
Net loss per share attributable to Common Stockholders, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.14)</u>	<u>\$ (1.07)</u>	<u>\$ (0.38)</u>

* Basic and diluted weighted-average common shares outstanding for the three and nine months ended September 30, 2022, have been computed based on the historical weighted-average common shares outstanding multiplied by the exchange ratio established in the Business Combination.

The potential shares of Common Stock that were excluded from the computation of diluted net loss per share attributable to Common Stockholders for the three and nine months ended September 30, 2023 and 2022 because including them would have been antidilutive are as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Common Stock upon conversion of redeemable convertible preferred stock A	—	4,214,422	—	4,214,422
Common Stock upon conversion of redeemable convertible preferred stock B	—	7,288,333	—	7,288,333
Non-vested shares of Series C common stock	—	638,972	—	638,972
Warrants to purchase redeemable convertible preferred stock B, as-converted	—	322,223	—	322,223
Series A Preferred Stock	9,526,000	—	9,526,000	—
Warrants to purchase Common Stock	11,066,611	—	11,066,611	—
Options to purchase Common Stock	1,465,817	—	1,465,817	—
Senior Convertible Notes	5,858,842	—	5,858,842	—
Subordinated Convertible Notes	<u>13,032,835</u>	<u>—</u>	<u>13,032,835</u>	<u>—</u>
Total	<u>40,950,105</u>	<u>12,463,950</u>	<u>40,950,105</u>	<u>12,463,950</u>

In October 2023, in connection with the third closing of the Financing Transaction (see Note 7), the Company issued 900 shares of Series A Preferred Stock and warrants that will be exercisable to purchase 900,000 shares of Common Stock to a Noteholder Investor in exchange for cash consideration of \$900,000.

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

Cautionary Note on Forward-Looking Statements

This report, including, without limitation, statements under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "plans," "may," "will," "potential," "projects," "predicts," "continue," or "should," or, in each case, their negative or other variations or comparable terminology. There can be no assurance that actual results will not materially differ from expectations. Such statements include, but are not limited to:

- uncertainty of the projected financial information with respect to ProSomnus;
- ProSomnus's ability to continue as a going concern;
- ProSomnus's ability to expand its sales network and product lines;
- ProSomnus's ability to maintain and grow its profit margin from sales of ProSomnus oral devices;
- ProSomnus's ability to expand internationally;
- the roll-out of ProSomnus's business and the timing of expected business milestones;
- ProSomnus's ability to formulate, implement and modify effective sales, marketing, and strategic initiatives to drive revenue growth;
- expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment;
- the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA;
- ProSomnus's ability to attract and retain key personnel;
- the increased obligations related to being a public company;
- ProSomnus's ability to comply with its debt covenants or successfully renegotiating such covenants;
- ProSomnus's ability to obtain additional funding;
- ProSomnus's plans and ability to regain compliance with the Nasdaq Listing Rules;
- the viability of ProSomnus's intellectual property and intellectual property created in the future;
- government regulations and ProSomnus's ability to obtain applicable regulatory approvals and comply with government regulations, including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration; and
- the outcome of any legal proceedings that may be instituted against ProSomnus.

The forward-looking statements contained in this report are based on our current expectations and beliefs concerning future developments and their potential effects on us. Future developments affecting us may not be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) and other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors," which are incorporated by reference herein. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable law. These risks and others described under "Risk Factors" may not be exhaustive.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and developments in the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this report. In addition, even if our results or operations, financial condition and liquidity, and developments in the industry in which we operate are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in subsequent periods.

Overview

We are a medical technology company focused on the development, manufacturing and marketing of precision intraoral medical devices, a new option for treating and managing patients with mild to moderate Obstructive Sleep Apnea (“OSA”). Each ProSomnus precision intraoral device is personalized based on the anatomy and treatment plan for each patient. Our patented precision devices are engineered to create unique, consistent and predictable biomechanical advantages that lead to effective, comfortable, economical and patient preferred treatment outcomes for patients with OSA.

Our ProSomnus precision intraoral devices are classified by the U.S. Food and Drug Administration (the “FDA”) as Class II medical devices for the treatment of snoring and mild to moderate OSA. We received pre-market notification and FDA clearance pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) for our first intraoral device in July 2014 and our devices have been commercially available in the United States since August 2014. To date, over 200,000 ProSomnus precision devices have been prescribed for patients.

Sleep apnea is a serious and chronic respiratory disease that negatively impacts a patient’s sleep, health, and quality of life. OSA is the most common form of sleep apnea. OSA is a medical condition characterized by a cessation of breathing when the tongue, soft palate, and other related tissues in the back of the throat collapse and block the upper airway during sleep, temporarily decreasing the oxygen concentration in the blood. During an OSA episode, the diaphragm and chest muscles must work harder to overcome the obstruction and open the airway. These episodes disrupt the sleep cycle, reduce airflow to vital organs, stress the body, and create a negative feedback loop. If untreated, OSA increases the risk of high blood pressure, hypertension, heart failure, stroke, coronary artery disease and other life-threatening diseases. OSA is associated with a reduction in quality-of-life factors including a higher risk of motor vehicle and operator accidents, workplace errors, absenteeism and more.

Until ProSomnus, there have been few alternatives for OSA patients who refuse or fail CPAP. Historically, treatment alternatives to CPAP have consisted of surgical procedures or legacy dental products. Surgical procedures, such as hypoglossal nerve stimulation and maxillomandibular advancement, are invasive and can be, irreversible, expensive, and only suitable for a narrow range of patient types. Legacy dental products, historically, have been associated with inconsistent and unreliable performance. We believe that there is both an urgent clinical need and a strong market opportunity for a treatment alternative that is effective, non- surgical, convenient, and more economical.

ProSomnus therapy is covered by most private insurance payers, Medicare, and by a growing number of public health insurance programs offered in many countries around the world. In the United States an estimated 70% of treatments are paid for by private insurance, 25% are covered by Medicare and the remaining 5% are paid out of pocket by the patient.

Providers are typically reimbursed by private medical insurance in the range of approximately \$2,000 to \$3,500 per patient for intraoral appliance therapy and by Medicare in the range of approximately \$1,250 to \$1,800 per patient for intraoral appliance therapy. The average amount varies by insurance provider and Medicare jurisdiction. At these reimbursement levels, we believe that intraoral appliance therapy offers dentists an attractive ratio of revenue per chair time in comparison to other dental procedures.

We market and sell our precision intraoral devices to sleep medicine providers in the United States and in select countries around the world through a direct sales force. We currently have 36 direct sales representatives in the United States, Canada, and Europe. Our sales force focuses their education, promotional and sales efforts on dentists who have developed a specialty in dental sleep medicine, and the physicians who are actively treating OSA.

We generated revenue of \$7.1 million and a net loss of \$11.2 million for the three months ended September 30, 2023, compared to revenue of \$5.0 million and a net loss of \$3.5 million for the three months ended September 30, 2022. We generated revenue of \$19.8 million and a net loss of \$17.2 million for the nine months ended September 30, 2023, compared to revenue of \$13.6 million and a net loss of \$9.4 million for the nine months ended September 30, 2022. Accumulated deficit as of September 30, 2023 was \$228.0 million.

Macroeconomic Environment

Uncertainty surrounding macroeconomic and geopolitical factors in the U.S. and globally characterized by the supply chain environment, inflationary pressure, higher interest rates, instability in the global financial markets, labor shortages, significant

disruptions in the commodities' markets as a result of the military conflicts in Ukraine and the Middle East, and the introduction of or changes in tariffs or trade barriers may result in a recession, which could have a material adverse effect on our long-term business.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. financial institutions, and our deposits exceed insured limits. Market conditions could impact the viability of these institutions. To date, these market conditions and liquidity concerns have not impacted our results of operations. However, in the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Recent Financing Transaction

On September 20, 2023, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement", and the transactions contemplated by the Securities Purchase Agreement, the "Financing Transaction") with certain third-party and related party investors (the "Investors"), pursuant to which we issued (i) an aggregate of 10,426 shares of Series A Preferred Stock, par value \$0.0001 per share (the "Series A Preferred Stock"), for an aggregate purchase price of \$10.4 million at a per share purchase price of \$1,000, and (ii) (A) with respect to Investors that held the Existing Convertible Notes, new convertible notes on substantially similar terms to such Noteholder Investor's Existing Convertible Notes other than that such new notes will be convertible into shares of the Company's common stock, par value \$0.0001 ("Common Stock"), at a conversion price of \$1.00 per share subject to the terms and conditions of the applicable new indenture pursuant to which the applicable series of New Notes have been issued (the "New Notes"), in exchange for such Noteholder Investor's portion of the principal amount outstanding of the Existing Notes (the "Exchanges") pursuant to the Exchange Agreements and/or (B) warrants to purchase shares of Common Stock at an exercise price of \$1.00 per share (such warrants, the "Transaction Warrants").

The Investors include certain members of our board of directors ("Board of Directors") and certain of our executive officers, as well as affiliates and investment vehicles for such persons that held our Existing Convertible Notes. Convertible Noteholders representing approximately \$3.4 million in principal amount of the Senior Convertible Notes and approximately \$12.1 million in principal amount of the Subordinated Convertible Notes participated in the Financing Transaction.

The Financing Transaction closed on multiple dates: September 20, 2023, September 26, 2023, and October 20, 2023. The exchange of the Existing Convertible Notes, including the entrance into the indentures governing the New Notes, occurred on October 11, 2023.

As a result of the Financing Transaction, in September 2023, the Noteholder Investors effectively contributed an aggregate of \$6.4 million of cash to the Company in exchange for 6,376 shares of Series A Preferred Stock, Transaction Warrants exercisable into an aggregate of 1,404,524 shares of Common Stock, and the repricing of the conversion feature of their Convertible Notes, while the other Investors contributed an aggregate of \$3.2 million of cash to us in exchange for 3,150 shares of Series A Preferred Stock and Transaction Warrants exercisable into an aggregate of 3,150,000 shares of Common Stock.

Factors Affecting Results of Operations

The following factors have been important to our business, and we expect them to impact our results of operations and financial condition in future periods:

(a) Expansion of North American direct sales organization and international expansion

The core focus of our sales initiative is to expand our direct sales organization in North America. With representatives located in high-value metropolitan areas, the direct sales organization will focus primarily on dentists and physicians who are practicing sleep medicine. The main purpose of this initiative is to increase case volume from these dentists and physicians by facilitating a referral relationship between dentists and physicians, helping them expand the dental sleep medicine aspect of their practices and educating them on the advantages of the ProSomnus intraoral devices. We also intend to further expand our sales to integrated health systems and hospital networks. We are currently initiating the marketing and sales of our ProSomnus intraoral devices in several European countries and intend to further expand our marketing and direct sales into international markets.

(b) Product line extensions and remote patient monitoring services

We intend for product line extensions to focus on enabling ProSomnus to capture a larger share of treatments for patients with OSA, snoring and other related sleep disordered breathing conditions. We expect that each product line extension will be designed to optimize ProSomnus products for a wider range of case types, treatment philosophies, and indications. We expect that each product line extension will utilize our unique manufacturing platform and potentially create additional opportunities for intellectual property.

We received FDA clearance for an intraoral device that enables remote patient monitoring services in November 2020. The sales of such remote patient monitoring services in connection with our intraoral devices could result in an additional recurring revenue stream that is reimbursable by insurance. Our remote patient monitoring services will be based on the incorporation of a sensor into the ProSomnus intraoral devices that provides continuous monitoring of physiological health data that physicians want and cannot typically obtain from CPAP or other intraoral appliance therapy devices. Our market research indicates that our remote patient monitoring services could be a significant driver of greater market acceptance and expansion and result in significant future revenues.

Description of Certain Components of Financial Data

Revenue

We derive primarily all of our revenue from the sale of our customized precision intraoral medical devices that clinicians use to treat patients diagnosed with Obstructive Sleep Apnea. Our revenue recognition policies are discussed in more detail in Note 2 to our condensed consolidated financial statements and notes thereto for the three and nine months ended September 30, 2023 and 2022 included elsewhere in this quarterly report.

Cost of revenue

Cost of revenue consists primarily of materials and the costs related to the production of the intraoral device, including employee compensation, other employee-related expenses, inbound shipping and allocable manufacturing overhead costs. ProSomnus has a policy to classify initial recruiting and training costs of new manufacturing employees as part of research and development expenses in the consolidated statements of operations.

Sales and marketing

Sales and marketing costs primarily consist of salaries, bonuses, benefits and travel costs for employees engaged in sales and marketing activities, as well as website, advertising, conferences and other promotional costs. We expect sales and marketing expenses to continue increasing in absolute dollars as we expand our sales organization both domestically and internationally.

Research and development

Research and development costs consist of production costs for prototypes, test and pre-production units, supplies, consulting, and personnel costs, including salaries, bonuses and benefit costs. Most of our research and development expenses are related to developing new products and services. Consulting expenses are related to research and development activities as well as clinical and regulatory activities and certain third-party engineering costs. Research and development expenses are expensed as incurred. We expect to continue to make substantial investments in product development. As a result, research and development expenses are expected to increase in absolute dollars as the research and development efforts increase.

General and administrative

General and administrative expenses primarily consist of labor, bonuses, benefits, general insurance, office expenses and outside services. Outside services consist of audit, tax, legal and other professional fees. We expect that general and administrative expenses will increase in absolute dollars as a result of operating as a public company.

Other income (expense)

Other income (expense) primarily relates to interest expense as well as the change in fair value of our convertible debt, earnout liability, warrants classified as liabilities, losses on the extinguishment of debt, and other financing costs.

The components of interest expense include interest expense incurred under our Convertible Notes, subordinated notes, subordinated loan and security agreements, unsecured subordinated promissory notes, equipment financing and capital lease obligations.

Results of Operations

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

	Three Months Ended September 30,		Change	
	2023	2022	\$	%
Revenue	\$ 7,071,445	\$ 4,997,979	\$ 2,073,466	41.5 %
Cost of revenue	3,580,073	2,540,288	1,039,785	40.9 %
Gross profit	3,491,372	2,457,691	1,033,681	42.1 %
Gross margin %	49%	49%		
Operating expenses:				
Research and development	1,040,065	688,540	351,525	51.1 %
Sales and marketing	3,240,511	2,319,362	921,149	39.7 %
General and administrative	3,426,872	1,577,049	1,849,823	117.3 %
Total expenses	7,707,448	4,584,951	3,122,497	68.1 %
Other income (expense)				
Interest expense	(1,489,286)	(1,421,702)	(67,584)	4.8 %
Change in fair value of earnout liability	3,880,000	—	3,880,000	n/m
Change in fair value of debt	3,699,737	—	3,699,737	n/m
Change in fair value of warrant liability	593,621	—	593,621	n/m
Loss on extinguishment of debt	(9,743,043)	—	(9,743,043)	n/m
Other expense	(3,963,756)	—	(3,963,756)	n/m
Total other income (expense)	(7,022,727)	(1,421,702)	(5,601,025)	394.0 %
Net loss before income taxes	(11,238,803)	(3,548,962)	(7,689,841)	216.7 %
Net loss	<u>\$ (11,238,803)</u>	<u>\$ (3,548,962)</u>	<u>\$ (7,689,841)</u>	<u>216.7 %</u>

(n/m = not meaningful)

Revenue for the three months ended September 30, 2023 totaled \$7.1 million, reflecting a 41.5% increase over \$5.0 million reported for the same period in 2022. This increase was primarily driven by increased unit volume due to increased sales and marketing investments and mix shift to the new EVO Products. We believe the underlying growth in product sales is attributable to the growing clinical adoption of ProSomnus's precision devices in both the United States and Europe and positive impacts of the expanded field sales team during the first half of 2023.

Our gross margin remained relatively consistent for the three months ended September 30, 2023, compared to three months ended September 30, 2022 at 49%. We moved into a new manufacturing facility during 2023. The facility quadrupled our previous capacity and increased overhead costs absorbed into product costs. As volumes increase, we expect to be able to leverage the new facility to improve the gross margin.

Sales and marketing expense increased by \$0.9 million, or 39.7%, for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was primarily driven by an increase in personnel expenses due to expansion of the sales team and travel and in-person events.

[Table of Contents](#)

Research and development expense increased by \$0.4 million, or 51.1%, for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was primarily driven by an increase in headcount-related personnel and research and development.

General and administrative expense increased by \$1.8 million, or 117.3%, for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This increase was driven primarily by professional services and legal fees of \$0.9 million, headcount-related personnel costs of \$0.6 million, and \$0.3 million of various other expenses.

Other income (expense) increased by \$4.0 million for the three months ended September 30, 2023 compared to the same prior period as a result of a \$2.5 million financing loss and a \$1.5 million write-off of debt financing costs in connection with our September 2023 Financing Transaction.

Total other expense increased by \$5.6 million for the three months ended September 30, 2023 compared to the same prior period. The increase was primarily driven by the debt extinguishment and other financing losses and costs incurred related to the Financing Transaction totaling \$13.7 million offset by the recognition of decreases in the fair value of the earnout liability of \$3.9 million, our Convertible Notes of \$3.7 million, and the warrant liability of \$0.6 million.

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

	Nine Months Ended September 30,		Change	
	2023	2022	\$	%
Revenue	\$ 19,813,735	\$ 13,601,031	\$ 6,212,704	45.7 %
Cost of revenue	9,507,498	6,440,475	3,067,023	47.6 %
Gross profit	10,306,237	7,160,556	3,145,681	43.9 %
Gross margin %	52%	53%		
Operating expenses:				
Research and development	3,435,070	1,915,521	1,519,549	79.3 %
Sales and marketing	9,707,277	6,450,173	3,257,104	50.5 %
General and administrative	11,260,003	4,219,938	7,040,065	166.8 %
Total operating expenses	24,402,350	12,585,632	11,816,718	93.9 %
Other income (expense)				
Interest expense	(3,901,255)	(3,714,777)	(186,478)	5.0 %
Change in fair value of earnout liability	12,080,000	—	12,080,000	n/m
Change in fair value of debt	1,070,307	—	1,070,307	n/m
Change in fair value of warrant liability	1,857,460	(20,756)	1,878,216	n/m
Loss on extinguishment of debt	(9,743,043)	(192,731)	(9,550,312)	n/m
Other expense	(4,493,400)	—	(4,493,400)	n/m
Total other income (expense)	(3,129,931)	(3,928,264)	798,333	(20.3)%
Net loss before income taxes	(17,226,044)	(9,353,340)	(7,872,704)	84.2 %
Net loss	<u>\$ (17,226,044)</u>	<u>\$ (9,353,340)</u>	<u>\$ (7,872,704)</u>	<u>84.2 %</u>

(n/m = not meaningful)

Revenue increased by \$6.2 million, or 45.7%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was primarily driven by increased unit volume due to increased sales and marketing investments and mix shift to the new EVO Products. We believe the underlying growth in product sales is attributable to the growing clinical adoption of ProSomnus's precision devices in both the United States and Europe and positive impacts of the expanded field sales team during the first half of 2023.

Our gross margin remained consistent for the nine months ended September 30, 2023 at 52% compared to 53% for the same prior period. We moved into a new manufacturing facility during 2023. The facility quadrupled our previous capacity and increased overhead costs absorbed into product costs. As volumes increase, we expect to be able to leverage the new facility to improve the gross margin.

Sales and marketing expense increased by \$3.3 million, or 50.5%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was primarily driven by an increase in personnel expenses due to the expansion of the sales team and travel and in-person events.

Research and development expense increased by \$1.5 million, or 79.3%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was primarily driven by an increase in headcount-related personnel and research and development.

General and administrative expense increased by \$7.0 million, or 166.8%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This increase was driven primarily by professional services and legal fees of \$2.3 million, headcount-related personnel costs of \$2.1 million, higher occupancy costs of \$0.6 million primarily related to our new headquarters, and \$2.0 million of various other costs.

Total other expense decreased by \$0.8 million, or 20.3%, from \$3.9 million for the nine months ended September 30, 2022, to \$3.1 million for nine months ended September 30, 2023. This change was primarily driven by decreases in the fair value of the earnout liability of \$12.0 million, Convertible Notes of \$1.1 million, and warrant liability of \$1.9 million, offset by debt extinguishment and other financing losses and costs incurred related to the Financing Transaction totaling \$13.7 million.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern and Management's Plans

Our liquidity needs are to fund our ongoing business initiatives. Historically, our sources of cash were primarily the issuance of equity securities and the incurrence of debt and our uses of cash were to fund our operating needs and to service our indebtedness. We expect to use our existing cash to, among other things, (i) continue expanding our direct sales organization, (ii) expand internationally, (iii) develop our brand and marketing, (iv) develop scientific data to further validate our products, (v) expand and develop our product lines, (vi) fund our debt payment obligations, and (vii) provide for general corporate purposes. We have incurred recurring losses from operations and recurring negative cash flows from operating activities. We expect operating losses and negative cash flows from operations to continue for the foreseeable future.

Our ability to continue as a going concern depends on our ability to execute on our plans to achieve revenue growth forecast, control operating costs, and obtain additional financing. We have developed a cash flow breakeven plan pursuant to which we expect to maintain positive cash balances and compliance with debt covenants and commitments. We have commenced the implementation of our plan and believe the plan, when fully implemented as planned, will mitigate the liquidity risks identified. However, our operating plan may change as a result of many factors currently unknown and there can be no assurance that the current operating plan or cash flow break even plan will be achieved in the time frame anticipated by us. Furthermore, there can be no assurance that we will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all.

Based on our current level of expenditures and management's future cash flow projections, we believe our cash and cash equivalents of \$12.0 million and working capital of \$6.1 million at September 30, 2023, may not be sufficient for us to continue operations as a going concern for at least one year from the issuance date of these condensed consolidated financial statements. Additionally, from July 1, 2023, the Convertible Notes require us to maintain a minimum cash balance of \$4.5 million on the first of each calendar month. We believe that without the successful and full implementation of our cash flow breakeven plan, these factors raise substantial doubt about our ability to continue as a going concern.

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (10,315,563)	\$ (4,762,394)
Investing activities	(1,903,242)	(331,373)
Financing activities	8,324,572	5,753,988
Net change in cash and cash equivalents	<u>\$ (3,894,233)</u>	<u>\$ 660,221</u>

Net cash used in operating activities

Cash flows from operating activities can fluctuate significantly from period to period, as net income (loss), adjusted for non-cash items, and working capital fluctuations impact cash flows. For the nine months ended September 30, 2023, net cash used in operating activities amounted to \$10.3 million compared to \$4.8 million in the same prior period. The increase was driven by higher operating expenses, primarily general and administrative expenses such as professional fees and legal costs, and to a lesser extent by higher spending on sales and marketing and research and development activities.

Net cash used in investing activities

For the nine months ended September 30, 2023 and 2022, net cash used in investing activities of \$1.9 million and \$0.3 million, respectively, was entirely related to purchases of property and equipment.

Net cash provided by financing activities

For the nine months ended September 30, 2023, net cash provided by financing activities amounted to \$8.3 million compared to \$5.8 million for the same prior period. The increase in cash provided by operating activities was primarily due to the Financing Transaction which resulted in cash proceeds of \$9.5 million. For the nine months ended September 30, 2022, net cash provided by financing activities of \$5.8 million primarily consisted of net proceeds from various debt financings which existed prior to the closing of our Business Combination in 2022 offset by \$0.8 million of principal payments under finance leases.

Contractual Obligations

Below is a summary of short-term and long-term anticipated cash requirements under contractual obligations existing as of September 30, 2023:

	As of September 30, 2023		
	2023 (remaining three months)	After December 31, 2023	Total
Recorded contractual obligations:			
Senior Convertible Notes	\$ —	\$ 16,959,807	\$ 16,959,807
Subordinated Convertible Notes	—	18,984,812	18,984,815
Other*	969,565	11,796,387	12,765,952
Total	<u>\$ 969,565</u>	<u>\$ 47,741,006</u>	<u>\$ 48,710,574</u>

*(1) Represents finance and operating lease liabilities, equipment financing obligations

As of September 30, 2023, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period.

There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates described in our Annual Report on Form 10-K for the year ended December 31, 2022. For more information, please refer to our Annual Report on Form 10-K as well as “Note 2—Basis of Accounting and Significant Accounting Policies” to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Emerging Growth Company and Smaller Reporting Company Status

ProSomnus is an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the “**JOBS Act**”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards.

The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. ProSomnus has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, ProSomnus, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of ProSomnus’s financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares held by non-affiliates exceeds \$250 million as of the prior June 30 or (ii) our annual revenue exceeded \$100 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of the prior June 30.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of business. Market risk represents the risk of loss that may impact our results of operations or financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold, issue, or enter into any financial instruments for speculative or trading purposes.

Interest rate risk

Our cash and cash equivalents as of September 30, 2023 consisted of \$12.0 million in bank accounts. We believe that we do not have any material exposure to changes in the fair value of these assets. We do not believe that a hypothetical 10% change in interest rates would have a material effect on our consolidated cash flows or operating results.

Our Subordinated Convertible Notes bear variable interest rate at Prime Rate plus an additional 9% per annum. As a result, as interest rates increase, our interest expense increases. The interest on our Subordinated Convertible Notes is paid-in-kind quarterly; therefore, increasing interest rates result in increases in the outstanding balance of the Subordinated Convertible Notes.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development expenses.

We do not believe inflation has had a material effect on our results of operations for the periods presented in this filing.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our CEO and CFO concluded that, as of September 30, 2023, due to the material weakness described in our Annual Report on Form 10-K for the year ended December 31, 2022, our disclosure controls and procedures were not effective.

Inherent Limitations on Effectiveness of Controls

Our management, including our CEO and our CFO, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. 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. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or 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. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on 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. Projections of any evaluation of control effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

To the knowledge of our management, there is no litigation currently pending or contemplated against us, any of our officers or directors in their capacity as such or against any of our property.

Item 1A. Risk Factors

Investing in our Common Stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our condensed consolidated financial statements and accompanying notes, before making a decision to invest in our Common Stock. Our business, financial condition, results of operations, or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material. If any of the risks actually occur, our business, financial condition, results of operations, and prospects could be adversely affected. In that event, the trading price of our Common Stock could decline, and you could lose part or all of your investment.

Summary Risk Factors

You should consider all the information contained in this Quarterly Report on Form 10-Q before investing in our Common Stock. In particular, you should consider the risk factors described under “*Risk Factors*” beginning on page 11. Such risks include, but are not limited to, the following risks subsequent to the Business Combination:

Risks Related to Our Business and Industry

- We have a limited operating history;
- we have a history of operating losses;
- the need to raise additional capital;
- we have identified a historical material weakness in our internal control over financial reporting;
- we will not be successful if our devices are not sufficiently adopted by the medical and dental communities;
- a substantial portion of our revenue is from sales of a single type of product;
- the market for treating OSA is highly competitive and evolving rapidly;
- risks relating to public health conditions;
- failure to educate or train a sufficient number of physicians and dentists;
- our ability to respond in a timely and cost-effective manner to changes in the preferences of dentists or patients;
- business and results of operations may be impacted by the extent to which patients achieve and maintain adequate levels of government and third-party insurance reimbursement;
- precision intraoral medical devices are currently not recommended by most sleep physicians;
- our precision intraoral medical devices may become obsolete;
- potential international sales are subject to a number of risks;
- the maintenance of single supply relationships for certain of our key machines and raw materials; and
- failure of dentists to pay for their purchases on a timely basis.

Risks Related to Intellectual Property

- Dependence on patents and proprietary technology;
- confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information;
- intellectual property infringement claims;
- failure to secure trademark registrations; and
- claims that our employees have wrongfully used or disclosed alleged trade secrets.

Risks Related to Government and Regulation

- Expense of clinical trials that may be required to support regulatory submissions in the United States;
- results of clinical trials may not support further clinical development or commercialization;
- modifications to our precision intraoral medical devices may require additional FDA approvals;
- our precision intraoral medical devices are subject to extensive governmental regulation;
- relationships with dentists, other healthcare providers, and third-party payors will be subject, to federal and state healthcare fraud and abuse laws; and
- misuse or off-label use of our precision intraoral medical devices.

The Ownership of Our Securities

- Our ability to meet the continued listing requirements of Nasdaq;
- concentration of ownership among our officers, directors and their affiliates;
- future sales of a substantial number of shares of our Common Stock in the public market;
- the exercise of registration rights granted in connection with the Business Combination;
- there is no guarantee that our warrants will be in the money, and they may expire worthless;
- our ability to issue common and preferred stock without further stockholder approval;
- the absence of cash dividends in the future;
- volatility in the trading price of our securities;
- analyst coverage of our securities; and
- anti-takeover provisions in our governing documents.

Risks Related to Our Business and Industry

Our business has a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. As such, you cannot rely upon our historical operating performance to make an investment or voting decision regarding ProSomnus.

We began conducting our current business in 2016 and, as such, have a limited operating history and must be evaluated in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown obstacles. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in emerging and rapidly changing industries. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition, and results of operations could be adversely affected.

We have a history of operating losses and may never achieve cash flow positive or profitable results of operations.

Since we began our ProSomnus business in 2016, we have not been profitable and have incurred losses and cash flow deficits. For the fiscal years ended December 31, 2022 and 2021, we reported net losses of \$7.1 million and \$6.0 million, respectively, and negative cash flow from operating activities of \$10.3 million and \$4.6 million, respectively. Our unaudited condensed consolidated financial statements as of September 30, 2023 have been prepared under the assumption that we will continue as a going concern for the next twelve months. As of September 30, 2023, we had cash and cash equivalents of \$12.0 million and an accumulated deficit of \$228.0 million.

Our ability to continue as a going concern depends on our ability to execute on our plans to achieve revenue growth forecast, control operating costs, and obtain additional financing. We have developed a cash flow breakeven plan pursuant to which we expect to maintain positive cash balances and compliance with debt covenants and commitments. We have commenced the implementation of our plan and believe the plan, when fully implemented as planned, will mitigate the liquidity risks identified. However, our operating plan may change as a result of many factors currently unknown and there can be no assurance that the current operating plan or cash flow break

even plan will be achieved in the time frame anticipated by us. Furthermore, there can be no assurance that we will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all.

Based on our current level of expenditures and management's future cash flow projections, we believe our cash and cash equivalents of \$12.0 million and working capital of \$6.1 million at September 30, 2023, may not be sufficient for us to continue operations as a going concern for at least one year from the issuance date of these condensed consolidated financial statements. Additionally, from July 1, 2023, the Convertible Notes require us to maintain a minimum cash balance of \$4.5 million on the first of each calendar month. We believe that without the successful and full implementation of our cash flow breakeven plan, these factors raise substantial doubt about our ability to continue as a going concern.

We have identified a historical material weakness in our internal control over financial reporting.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021, we and our independent registered public accounting firms identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness in our case arose from the accounting for certain complex transactions and a lack of expertise for such accounting issues. While remediation efforts have been made, if we are unable to remedy our material weakness, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We will not be successful if our ProSomnus precision intraoral medical devices are not sufficiently adopted by the medical and dental communities for the treatment of Obstructive Sleep Apnea (OSA).

Our success depends both on the sufficient acceptance and adoption by the medical and dental communities of our ProSomnus precision intraoral medical devices as a non-invasive treatment for the treatment of mild to moderate OSA and potentially severe OSA in the future and on heightening public awareness of the prevalence of OSA to increase the number of undiagnosed patients who seek treatment. Currently, a relatively limited number of dentists and other medical professionals provide ProSomnus precision intraoral medical devices for the treatment of OSA. We cannot predict how quickly, if at all, the medical and dental communities will accept our precision intraoral medical devices, or, if accepted, the extent of their use.

For us to be successful:

- our providers and referring physicians must believe that the ProSomnus precision intraoral medical devices offer meaningful clinical and economic benefits for the treating provider and for the patient as compared to the other surgical and non-surgical procedures or devices currently being used to treat individuals with OSA, and referring physicians must write a prescription for the use of ProSomnus precision intraoral medical devices;
- our providers must use ProSomnus precision intraoral medical devices to treat OSA either as a stand-alone treatment, a treatment alternative for patients who fail or refuse CPAP, or in combination with procedures to treat other areas of upper airway obstruction and achieve acceptable clinical outcomes in the patients they treat;
- our providers must believe patients will pay for ProSomnus precision intraoral medical devices out-of-pocket or have qualifying medical insurance, and patients must believe that paying out-of-pocket or using their medical insurance for treatment is the best alternative to either doing nothing or entering into another treatment option; and
- our providers must be willing to commit the time and resources required to learn the new clinical and technical skills required to treat patients with OSA using ProSomnus precision intraoral medical devices.

Studies have shown that a significant percentage of people who have OSA remain undiagnosed and therefore do not seek treatment, or those who are diagnosed with OSA may be reluctant to seek treatment or incur costs of treatment, the potentially negative lifestyle effects of Continuous Positive Airway Pressure (CPAP) and other traditional treatments, and the lack of awareness of new treatment options. If the medical and dental communities are slow to adopt, or fail to adopt, ProSomnus precision intraoral medical devices as a treatment for individuals with OSA, we would suffer a material adverse effect on our business, financial condition, and results of operations.

We derive a substantial portion of our revenue from sales of a single type of product (ProSomnus precision intraoral medical devices) and expect to continue to do so, which leaves us reliant on the commercial viability of the ProSomnus precision intraoral medical devices.

Currently, our only products are ProSomnus precision intraoral medical devices. We expect a secondary source of revenue to be remote monitoring services, which we expect to introduce soon. We expect that sales of our ProSomnus precision intraoral medical devices will account for a significant amount of our revenue for the foreseeable future. We currently market and sell our ProSomnus precision intraoral medical devices primarily in the United States, Europe and Canada, with a very limited presence in Australia. Because the ProSomnus precision intraoral medical devices are different from current surgical and non-surgical treatments for OSA, we cannot assure you that dentists in corroboration with physicians will use our products, and demand for our products may decline or may not increase as quickly as we expect. Also, we cannot assure you that the ProSomnus precision intraoral medical devices will compete effectively as a treatment alternative to other more well-known and well-established therapies, such as CPAP, palatal surgical procedures, or other oral appliance therapy devices.

Since our ProSomnus precision intraoral medical devices currently represent our only products, we are significantly reliant on the level of recurring sales of the ProSomnus precision intraoral medical devices and decreased or lower than expected sales or recruitment of physicians and sleep dentists to recommend our products would have a material adverse effect on our business, financial condition, and results of operations.

We expect to introduce remote monitoring services soon. We may be unable to launch these new services on time, at all, or without significant additional expense, and such services may not be as popular as we anticipated, which would have a material adverse effect on our business, financial condition, and results of operations.

We face risks relating to public health conditions such as the COVID-19 pandemic, which could adversely affect our customers, sleep physicians, our business, and our results of operations.

Our business and prospects have been and could be materially adversely affected by the COVID-19 pandemic or recurrences of COVID-19, including new variants, or any other similar diseases in the future. Material adverse effects from COVID-19 and similar diseases could result in numerous known and currently unknown ways including from quarantines and lockdowns which impair our marketing and sales efforts to dentists or other medical professionals and limit patient visits to sleep dentists and physicians. During the COVID-19 pandemic, dental offices throughout the U.S. and Canada shut down for extended periods of time (and may be shut down again due to recurrences of COVID-19), thus negatively impacting our product revenues. The pandemic and reactions to the pandemic or future outbreaks of COVID-19 could also impair the timing of obtaining necessary consents and approvals from the FDA, as its employees could also be under such quarantines and lockdowns and their time could be mandatorily required to be allocated to more immediate global and domestic concerns relating to COVID-19. In addition, we purchase materials for our products from suppliers located in affected areas, and we may not be able to timely procure required materials. The effects of the COVID-19 pandemic have also placed travel restrictions on us, as well as temporary closures of the facilities of our suppliers as non-essential medical and dental procedures have been limited, which could also adversely impact our business. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could reduce the demand for our products and impair our business prospects including being unable to raise additional capital on acceptable terms to us, if at all.

We may not be able to successfully implement our growth strategy by successfully attracting sleep dentists and sleep physicians on a timely basis or at all, which could harm our business, financial condition, and results of operations.

The growth of our business depends on our ability to execute our plan to attract new sleep dentists and sleep physicians. Our ability to recruit sleep dentists and sleep physicians depends on many factors, including our ability to:

- achieve brand awareness in new and existing markets;
- convince sleep dentists and sleep physicians of the value of our products and services and to make the required investments in becoming a provider of ProSomnus precision intraoral medical devices;
- manage costs, which could give rise to delays or cost overruns;
- successfully educate qualified dentists, dental hygienists, physicians, physician assistants, medical technologists and other staff in our local markets on the benefits of our devices;

- obtain and maintain favorable reimbursement rates for our precision intraoral medical devices and remote monitoring services and for services rendered at dental or physician offices relating to our precision intraoral medical devices;
- remote monitoring services and for services rendered at dental or physician offices relating to our precision intraoral medical devices;
- develop new products and services;
- expand to new markets;
- outperform competitors; and
- maintain adequate information systems and other operational system capabilities.

Further, applicable laws, rules, and regulations (including licensure requirements) could negatively impact our ability to recruit sleep dentists that provide our devices to their patients.

Accordingly, we may not be able to achieve our planned growth or, even if we are able to grow our base of sleep dentists as planned, we may not be profitable or otherwise perform as planned. We may also struggle to recruit and train ProSomnus employees which could limit our ability to deliver product in a timely manner. Failure to successfully implement our growth strategy would likely have an adverse impact on our business, financial condition, and results of operations.

Our sales and marketing efforts may not be successful.

We currently market and sell our ProSomnus precision intraoral medical devices to a limited number of licensed professionals, primarily sleep dentists. Approximately 2.4% of dentists in the United States have been trained in providing our ProSomnus precision intraoral medical devices. The commercial success of our ProSomnus precision intraoral medical devices ultimately depends upon a number of factors, including the number of sleep dentists who provide our ProSomnus precision intraoral medical devices to their patients, the number of devices provided by these dentists, the number of patients who become aware of our ProSomnus precision intraoral medical devices by self-referral or referrals by their primary care or sleep physicians, the number of patients who elect to use our ProSomnus precision intraoral medical devices, and the number of patients who, having successfully used our ProSomnus precision intraoral medical devices, endorse and refer our ProSomnus precision intraoral medical devices to other potential patients.

Although we sell our products directly to sleep dentists, our experience in marketing and selling our ProSomnus precision intraoral medical devices through a direct sales organization in the United States is limited. We may not be able to maintain a suitable sales force in the United States or internationally or train a suitable number of sleep dentists and physicians. Our marketing and sales efforts may not be successful in increasing awareness and sales of our ProSomnus precision intraoral medical devices.

The failure to educate a sufficient number of physicians and dentists in the benefits and use of our ProSomnus precision intraoral medical devices could reduce the market acceptance of our ProSomnus precision intraoral medical devices and reduce our revenue.

It is critical to the success of our sales efforts that there is an increasing number of sleep dentists and sleep physicians familiar with and proficient in the use of our ProSomnus precision intraoral medical devices. Currently, sleep dentists learn to use our ProSomnus precision intraoral medical devices through hands-on, on-site training or virtual training by our representatives. However, to receive this training, dentists must be aware of our ProSomnus precision intraoral medical devices as a treatment option for OSA and be interested in using our ProSomnus precision intraoral medical devices in their practice. We cannot predict the extent to which dentists will dedicate the time and energy necessary for adequate training in the use of our ProSomnus precision intraoral medical devices, have the knowledge of or experience in the clinical outcomes of our ProSomnus precision intraoral medical devices, or feel comfortable enough using our ProSomnus precision intraoral medical devices to recommend it to their patients. Even if a dentist is well versed in our ProSomnus precision intraoral medical devices, he or she may be unwilling to require patients to pay for the oral device out-of-pocket if not covered by medical insurance. If dentists do not continue to accept and recommend our ProSomnus precision intraoral medical devices, our revenue could be materially and adversely affected.

Our marketing activities may not be successful.

We incur costs and expend other resources in our marketing efforts to attract and retain sleep dentists, referring physicians and patients. Our marketing activities are principally focused on increasing brand awareness in the communities in which we provide services. We expect to undertake marketing campaigns to increase awareness about our presence and our service capabilities. If we are not successful in these efforts, we will have incurred expenses without materially increasing revenue.

Our future operating results are difficult to predict and may vary significantly from quarter to quarter, which may adversely affect the price of our Common Stock.

Our limited history of sales of our ProSomnus precision intraoral medical devices, together with our history of losses, make prediction of future operating results difficult. You should not rely on our past revenue growth as any indication of future growth rates or operating results. Our valuation and the price of our securities likely will fall in the event our operating results do not meet the expectations of analysts and investors. Comparisons of our quarterly operating results are an unreliable indication of our future performance because they are likely to vary significantly based on many factors, including:

- our inability to attract demand for and obtain acceptance of our precision intraoral medical devices for the treatment of OSA by dentists, physicians, and patients;
- the success of alternative therapies and surgical procedures to treat individuals with OSA, and the possible future introduction of new products and treatments for OSA;
- our ability to maintain current pricing for our products;
- our ability to expand by recruiting additional sleep dentists and physicians in leading major metropolitan areas;
- the expansion and rate of success of our marketing and advertising efforts to patients, dentists and physicians, and the rate of success of our direct sales force in the United States and internationally;
- failure of suppliers to deliver machinery or raw materials or provide services in a cost effective and timely manner;
- our failure to develop, find, or market new products and/or services;
- the successful completion of current and future clinical studies, and the possibility that the results of any future study may be adverse to our product and services, or reveal some heretofore unknown risk to patients from treatment using our precision intraoral medical devices;
- actions relating to ongoing FDA compliance;
- the volume and timing of orders from dentists;
- our ability to obtain reimbursement for our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA from third-party healthcare insurers;
- the willingness of patients to pay out-of-pocket for treatment using ProSomnus precision intraoral medical devices in the absence of reimbursement from third-party healthcare insurers for the treatment of OSA;
- decisions by one or more commercial health insurance companies to preclude, deny, limit, reduce, eliminate, or curtail reimbursement for treatment in whole or part by our precision intraoral medical devices precision intraoral medical devices;
- unanticipated delays in the development and introduction of our future products and services and/or our inability to control costs;
- the effects of global or local pandemics or epidemics, such as COVID-19, and resulting governmental responses;
- seasonal fluctuations in revenue due to the elective nature of sleep-disordered breathing treatments, including our ProSomnus precision intraoral medical devices, as well as seasonal fluctuations resulting from adverse weather conditions, earthquakes, floods, or other acts of nature in certain areas or regions that result in power outages, transportation interruptions, damages to one or more of our facilities, food shortages, or other events which may cause a temporary or long-term disruption in patient priorities, finances, or other matters; and
- general economic conditions as well as those specific to our customers and markets.

We may not be able to respond in a timely and cost-effective manner to changes in the preferences of physicians, dental sleep medicine providers or patients.

Our ProSomnus precision intraoral medical devices are subject to changing preferences of both physicians and dental sleep medicine providers that provide our precisions intraoral medical devices to patients and the patients themselves. A shift in preferences away from the precision intraoral medical devices we offer would result in our results of operations in future periods to be materially adversely impacted.

Further clinical studies of our ProSomnus precision intraoral medical devices may adversely impact our ability to generate revenue if they do not demonstrate that our devices are clinically effective for currently specified or expanded indications or if they are not completed in a timely manner.

We have conducted a number of clinical studies of the use of our ProSomnus precision intraoral medical devices to treat patients with mild to moderate OSA in the United States, Europe and Canada. We are also involved in a number of ongoing clinical studies

evaluating clinical outcomes from the use of our ProSomnus precision intraoral medical devices, including prospective, randomized, placebo-controlled studies, as well as clinical studies that are structured to obtain additional clearances from the FDA for expanded clinical indications for use of our ProSomnus precision intraoral medical devices, including for the treatment of severe OSA.

We cannot assure you that these clinical studies will continue to demonstrate that our ProSomnus precision intraoral medical devices provide clinical effectiveness for individuals diagnosed with mild to moderate OSA or will demonstrate that such devices also provide clinical effectiveness for individuals diagnosed with severe OSA, nor can we assure you that the use of our ProSomnus precision intraoral medical devices will prove to be safe and effective in clinical studies under United States or international regulatory guidelines for any expanded indications. Additional clinical studies of our ProSomnus precision intraoral medical devices may identify significant clinical, technical, or other obstacles that will have to be overcome prior to obtaining clearance from the applicable regulatory bodies to market our ProSomnus precision intraoral medical devices for such expanded indications.

Individuals selected to participate in these further clinical studies must meet certain anatomical and other criteria to participate. We cannot assure you that an adequate number of individuals can be enrolled in clinical studies on a timely basis. Further, we cannot assure you that the clinical studies will be completed as planned. A delay in the analysis and publication of the positive outcomes data from these clinical studies, or the presentation or publication of negative outcomes data from these clinical studies, including data related to approval of our ProSomnus precision intraoral medical devices for expanded indications, may materially impact our ability to increase revenue through sales and negatively impact our stock price.

Our business and results of operations may be impacted by the extent to which patients using our ProSomnus precision intraoral medical devices achieve and maintain adequate levels of government and third-party insurance reimbursement.

The cost of treatments for OSA, such as CPAP, and most surgical procedures generally are covered and reimbursed in whole or part by government and third-party healthcare insurers. Our ProSomnus precision intraoral medical devices are customized oral appliances, most of which currently qualify for reimbursement for the treatment of mild to moderate OSA. Our ability to generate future revenue from additional sales of our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA may be materially limited by the extent to which reimbursement of our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA is available in the future. In addition, government and third-party healthcare insurers are increasingly challenging the prices charged for medical products and procedures. Any changes in this reimbursement system or reimbursement levels could materially affect our ability to continue to grow our business.

Reimbursement and healthcare payment systems in international markets vary significantly by country and reimbursement for our ProSomnus precision intraoral medical devices may not be available at all under either government or private reimbursement systems. If we are unable to achieve reimbursement approvals in international markets, it could have a negative impact on market acceptance of our ProSomnus precision intraoral medical devices and potential revenue growth in the markets in which these approvals are sought.

We face significant competition in the rapidly changing market for treating OSA, and we may be unable to manage competitive pressures.

The market for treating OSA, including sleep apnea in people of all ages, is highly competitive and evolving rapidly. We compete as a front-line therapy in the OSA treatment market for patients with mild to moderate OSA. According to the American Sleep Apnea Association, over 100 different oral appliances are FDA cleared for the treatment of snoring and obstructive sleep apnea. Our ProSomnus precision intraoral medical devices must compete with more established products, treatments, and surgical procedures, which may limit our growth and negatively affect our business. Many of our competitors have an established presence in the field of treating OSA and have established relationships with pulmonologists, sleep clinics, and ear, nose and throat specialists (“ENTs”), which play a significant role in determining which product, treatment, or procedure is recommended to the patient. We believe certain of our competitors are attempting to develop innovative approaches and new products for diagnosing and treating. We cannot predict the extent to which ENTs, oral maxillofacial surgeons, primary care physicians, or pulmonologists would or will recommend our ProSomnus precision intraoral medical devices over new or other established devices, treatments, or procedures.

Moreover, we are in the early stages of implementing our business plan and have historically had limited resources with which to market, develop and sell our ProSomnus precision intraoral medical devices. Many of our competitors have substantially greater financial and other resources than we do, including larger research and development staffs who have more experience and capability in conducting research and development activities, testing products in clinical trials, obtaining regulatory approvals, and manufacturing.

marketing, selling, and distributing products. Some of our competitors may achieve patent protection, regulatory approval, or product commercialization more quickly than we do, which may decrease our ability to compete. If we are unable to be competitive in the market for OSA, our revenue will decline, which would negatively affect our results of operations.

Our ProSomnus precision intraoral medical devices may become obsolete if we are unable to anticipate and adapt to rapidly changing technology.

The medical device industry is subject to rapid technological innovation and, consequently, the life cycle of any particular product can be short. Alternative products, procedures, or other discoveries and developments to treat OSA may render our ProSomnus precision intraoral medical devices obsolete.

Furthermore, the greater financial and other resources of many of our competitors may permit them to respond more rapidly than we can to technological advances. If we fail to develop new technologies, products, or services to upgrade or improve our existing ProSomnus precision intraoral medical devices to respond to a changing market before our competitors are able to do so, our ability to market our products and generate substantial revenue may be limited.

Our potential international sales are subject to a number of risks that could seriously harm our ability to successfully commercialize our ProSomnus precision intraoral medical devices in international markets.

We do not have any significant international sales outside of Europe and Canada, although we hope to more broadly introduce our ProSomnus precision intraoral medical devices into international markets in the future. Our ability to generate international sales is subject to several risks, including:

- our ability to recruit and train the appropriate staff;
- our ability to obtain appropriate regulatory approvals to market our ProSomnus precision intraoral medical devices in certain countries;
- our ability to identify sleep dentists and sleep physicians in international markets;
- the impact of recessions in economies outside the United States;
- greater difficulty in negotiating with socialized medical systems, maintaining profit margins comparable to those achieved in the United States, collecting accounts receivable, and longer collection periods;
- unexpected changes in regulatory requirements, tariffs, or other trade barriers;
- weaker intellectual property rights protection in some countries;
- potentially adverse tax consequences; and
- political and economic instability.

The occurrence of any of these events could seriously harm our future international sales and our ability to successfully commercialize our products in international markets, thereby limiting our growth and revenue.

We maintain supply relationships for certain of our key manufacturing systems and raw materials, and our business and operating results could be harmed if supply is restricted or ends, or the price of raw materials used in our manufacturing process increases.

We are highly dependent on manufacturers of specialized oral scanning equipment, milling machines, and advanced medical grade raw materials for the fabrication of our precision intraoral medical devices. We maintain supply relationships for many of these systems and materials. We are also committed to purchasing the vast majority of our advanced medical grade Class VI polymer, the primary raw material used in our manufacturing of our precision intraoral medical devices, from a certain source. While it is our goal to have multiple sources to procure certain key components, in some cases it may not be economically practical or feasible to do so. To mitigate this risk, we maintain an awareness of alternate supply sources that could provide our components with minimal or no modification to the current version of our precision intraoral medical devices, practice supply chain management, maintain safety stocks of critical components and have arrangements with our key vendors to manage the availability of critical components. If these or other suppliers encounter financial, operating, or other difficulties or if our relationship with them changes, we might not be able to quickly establish or qualify replacement sources of supply and could face production interruptions, delays, and inefficiencies. In addition, technological changes by our vendors could disrupt our manufacturing process or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment

and materials in sufficient quantities to support our growth. Conversely, in order to secure supplies for production of our precision intraoral medical devices, we sometimes enter into non-cancelable purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If demand for our products is less than we expect, we may experience additional excess and obsolete inventories and be forced to incur additional charges and our profitability may suffer. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

The failure of dentists to pay for their purchases of our ProSomnus precision intraoral medical devices on a timely basis could reduce our future revenue and negatively impact our liquidity.

The timing and extent of our future growth in revenue depends, in part, on our ability to continue to increase the number of sleep dentists using our ProSomnus precision intraoral medical devices, as well as expanding the number of our ProSomnus precision intraoral medical devices used by these dentists. To the extent one or more of our large providers fails to pay us for our ProSomnus precision intraoral medical devices on a timely basis, we may be required to discontinue selling to these dentists and find new customers, which could reduce our future revenue and negatively impact our liquidity.

Our revenues may depend on our patients' and providers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.

Political, economic, and regulatory influences continue to change the medical device industry in the United States. The ability of patients to pay fees for our devices will partially depend on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third-party payors do not provide adequate coverage and reimbursement to physicians and care providers. Major third-party payors, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in adverse changes to reimbursement for certain specified devices, potentially adversely impacting our business, results of operations, and financial conditions.

The sales of our devices will depend in part on the availability of reimbursement by third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical devices and services. Governmental approval of medical products does not guarantee that these third-party payors will pay for the products. Even if third-party payors do accept our medical devices, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of devices may change before our products and services are approved for marketing, and any such changes could further limit reimbursement, if any.

Third-party payors often require billing clinicians to participate in the third-party payors network ("in-network") to receive the maximum benefit from the third-party payor. If our customer dentists and clinicians do not participate in third-party payor networks, costs to patients may increase materially and adversely and negatively impact our business by reducing patient willingness to pay out of pocket for our products resulting in reduced revenue.

We face the risk of product liability claims that could be expensive, divert management's attention, and harm our reputation and business.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing, and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our ProSomnus precision intraoral medical devices are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse, or abuse associated with our ProSomnus precision intraoral medical devices could potentially result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our ProSomnus precision intraoral medical devices cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with our ProSomnus precision intraoral medical devices, among others. If we cannot successfully defend ourselves

against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our ProSomnus precision intraoral medical devices or new products;
- decreased demand and brand reputation for our ProSomnus precision intraoral medical devices;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

Any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to maintain adequate product liability insurance.

Our product liability and clinical study liability insurance is subject to deductibles and coverage limitations. Our product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities.

We bear the risk of warranty claims on our ProSomnus precision intraoral medical devices.

We bear the risk of warranty claims on our ProSomnus precision intraoral medical devices. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers or patients related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

Risks Related to Intellectual Property

We depend on our patents and proprietary technology, which we may not be able to protect.

Our success depends, in part, on our ability to obtain and maintain patent protection for our ProSomnus precision intraoral medical devices and our manufacturing process and the confidentiality of proprietary technology. Our success further depends on our ability to obtain and maintain trademark protection for our name and mark, to preserve our trade secrets and know-how, and to operate without infringing the intellectual property rights of others.

We cannot assure investors that we will continue to innovate and file new patent applications, or that if any filed future patent applications will result in granted patents. We cannot assure you that any of our patents pending will result in issued patents, that any current or future patents will not be challenged, invalidated, or circumvented, that the scope of any of our patents will exclude competitors or that the patent rights granted to us will provide us any competitive advantage or protect our products. The patent position of device companies, including ours, is generally uncertain and involves complex legal and factual considerations and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, protocols and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Any patents we have obtained or obtain in the future may be challenged by re-examination or otherwise invalidated or found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. If we were to initiate legal proceedings against a third party to enforce a patent related to one of our products, the defendant in such litigation could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, as are validity challenges by the defendant against the subject patent or other patents before the United States Patent and Trademark Office (“USPTO”). Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement, failure to meet the written description requirement, indefiniteness, and/or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or made a misleading statement, during prosecution. Additional grounds for an unenforceability assertion include an allegation of misuse or anticompetitive use of patent rights, and an allegation of incorrect inventorship with deceptive intent. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome is unpredictable following legal assertions of invalidity and unenforceability. With respect to the validity question, for example, we cannot be certain that no invalidating prior art existed of which we and the patent examiner were unaware during prosecution. These assertions may also be based on information known to us or the USPTO. If a defendant or third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the claims of the challenged patent. Such a loss of patent protection would or could have a material adverse impact on our business.

The standards that the USPTO (and foreign equivalents) use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

However, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products or product candidates infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties’ patent rights.

In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property. We may fail to obtain any of these licenses or intellectual property rights on commercially reasonable terms. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

In addition to patents, we rely on trademarks to protect the recognition of our company and products in the marketplace. We also rely on trade secrets, know-how, and proprietary knowledge that we seek to protect, in part, through confidentiality agreements with employees, consultants and others. We cannot assure you that our proprietary information will not be shared, our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or independently developed by competitors.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and disclosure of our trade secrets or proprietary information could compromise any competitive advantage that we have, which could have a materially adverse effect on our business.

Our success depends, in part, on our ability to protect our proprietary rights to the technologies used in our products and our proprietary technology. We depend heavily upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of our technology. These measures may not afford us complete or even sufficient protection and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business.

We may face intellectual property infringement claims that would be costly to resolve.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, and our competitors and others may initiate intellectual property litigation, including as a means of competition. Intellectual property litigation is complex and expensive, and outcomes are difficult to predict. We cannot assure you that we will not become subject to patent infringement claims, litigation, or interference proceedings to determine the priority of inventions. Litigation or regulatory proceedings also may be necessary to enforce our patent or other intellectual property rights. We may not always have the financial resources to assert patent infringement suits or to defend ourselves from claims. An adverse result in any litigation could subject us to liabilities or require us to seek licenses from or pay royalties to others that may be substantial. Furthermore, we cannot predict the extent to which the necessary licenses would be available to us on satisfactory terms, if at all.

Our failure to secure trademark registrations could adversely affect our ability to market our products and operate our business.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed registration, and we may not be able to maintain or enforce our registered trademarks. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our products and our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical device industry, we may employ individuals who were previously employed at other companies similar to ours, including our competitors or potential competitors. We may become subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Government and Regulation

Our failure to obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and products could delay or limit introduction of our products and result in failure to achieve revenue or maintain our ongoing business.

Our development activities and the manufacture and marketing of our ProSomnus precision intraoral medical devices are subject to extensive regulation for safety, efficacy, and quality by numerous government authorities in the United States and internationally. Before receiving FDA or foreign regulatory clearance to market our products which are not presently approved, we will have to demonstrate that these products are safe and effective in the patient population and for the indications that are to be treated. Clinical trials, manufacturing, and marketing of medical devices are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug, and Cosmetic Act and other federal, state, and foreign statutes and regulations

govern and influence the testing, manufacture, labeling, advertising, distribution, and promotion of medical devices. As a result, regulatory approvals for our products not yet approved or that we may develop in the future can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial, and other resources.

Clinical trials that may be required to support regulatory submissions in the United States are expensive. We cannot assure that we will be able to complete any required additional clinical trial programs successfully within any specific time period, and if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Conducting clinical trials is a lengthy, time-consuming, and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through clinical trials the safety and effectiveness of our products. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, product development, pilot trial testing, clinical trials, and regulated, compliant manufacturing processes.

Even if completed, we do not know if these trials will produce statistically significant or clinically meaningful results sufficient to support an application for marketing approval. If and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to advance the rate of patient enrollment, and the rate to collect, clean, lock, and analyze the clinical trial database.

Patient enrollment in trials is a function of many factors. These include the design of the protocol; the size of the patient population; the proximity of patients to and availability of clinical sites; the eligibility criteria for the study; the perceived risks and benefits of the product candidate under study; the medical investigators' efforts to facilitate timely enrollment in clinical trials; the patient referral practices of local physicians; the existence of competitive clinical trials; and whether other investigational, existing, or new products are available or cleared for the indication. If we experience delays in patient enrollment and/or completion of our clinical trial programs, we may incur additional costs and delays in our development programs and may not be able to complete our clinical trials on a cost-effective or timely basis. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all. If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Further, if we or any third party have difficulty enrolling a sufficient number of patients in a timely or cost-effective manner to conduct clinical trials as planned, or if enrolled patients do not complete the trial as planned, we or a third party may need to delay or terminate ongoing clinical trials, which could negatively affect our business.

The results of our clinical trials may not support either further clinical development or the commercialization of any new product candidates or modifications to existing products.

Even if our ongoing or contemplated clinical trials are completed as planned, their results may not support either the further clinical development or the commercialization of any new product candidates or modifications of existing products. The FDA or government authorities may not agree with our conclusions regarding the results of our clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results from any later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for indicated uses. This failure would cause us to abandon a product candidate or a modification to any existing product and may delay the development of other product candidates. Any delay in, or termination of, our clinical trials could delay the filing of our 510(k)'s and, ultimately, our ability to commercialize our product candidates and generate product revenue. Each Class I and Class II medical device marketed in the United States must receive a 510(k) clearance from the FDA. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective as, or substantially equivalent to, a legally marketed device. Companies must compare their device to one or more similar legally marketed devices, commonly known as "predicates," and make and support their substantial equivalency claims. The submitting company may not proceed with product marketing until it receives an order from the FDA declaring a device substantially equivalent.

The substantially equivalent determination is usually made within 90 days and is based on the information submitted by the applicant.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials. A number of companies in the medical technology industry have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products.

Modifications to our ProSomnus precision intraoral medical devices may require additional FDA approvals which, if not obtained, could force us to cease marketing and/or recall the modified device until we obtain new approvals.

After a device receives a 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a premarket approval (“PMA”). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Currently, we do not market devices within this Class III category, nor do we intend to in the foreseeable future. However, the FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer’s decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified devices until 510(k) clearance or PMA approval is obtained. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

Our ProSomnus precision intraoral medical device has received 510(k) Class II clearance from the FDA for treating mild to moderate OSA and snoring in adults.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations.

Although we are not currently subject to any FDA warning letters, censures or audits, we are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall, detention, or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for a 510(k) clearance of new products;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

The FDA also has the authority to request repair, replacement, or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Our ProSomnus precision intraoral medical devices are subject to extensive governmental regulation that could prevent us from selling our ProSomnus precision intraoral medical devices or introducing new and/or improved products and services in the United States or internationally.

Our precision intraoral medical devices, manufacturing activities, and remote monitoring services are subject to extensive regulation by a number of governmental agencies, including the FDA and comparable international regulatory bodies. We are required to:

- obtain clearance from the FDA and certain international regulatory bodies before we can market and sell our products;
- satisfy all content requirements for the sales and promotional materials associated with our ProSomnus precision intraoral medical devices; and
- undergo rigorous inspections of our facilities, manufacturing and quality control processes, records, and documentation.

Compliance with the rules and regulations of these various regulatory bodies may delay or prevent us from introducing any new models of our ProSomnus precision intraoral medical devices or other new products or services. In addition, government regulations may be adopted that could prevent, delay, modify, or rescind regulatory clearance or approval of our products.

Our manufacturing activities are further required to demonstrate compliance with the FDA's quality system regulations. The FDA enforces their quality system regulations through pre-approval and periodic post-approval inspections by representatives from the FDA. These regulations relate to product testing, vendor qualification, design control, and quality assurance, as well as the maintenance of records and documentation.

If we fail to conform to these regulations, the FDA may take actions that could seriously harm our business. These actions include sanctions, including temporary or permanent suspension of our operations, product recalls and marketing restrictions. A recall or other regulatory action could substantially increase our costs, damage our reputation, and materially affect our operating results.

Our relationships with dentists, other healthcare providers, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers (including dentists), physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation of our ProSomnus precision intraoral medical devices. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws, and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, sales, marketing, and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchasing, recommending, leasing, or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand, and physicians and patients on the other. The Patient Protection and Affordable Care Act, as amended (or the PPACA), amended the intent requirement of the federal Anti-Kickback Statute and, as a result, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (or HITECH), and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers, and their respective business associates;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (or CMS), information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws that require medical device companies to comply with the specific industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of our products from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The misuse or off-label use of our ProSomnus precision intraoral medical devices may harm our reputation in the marketplace, result in injuries that lead to product liability suits, or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

We train our marketing personnel and direct sales force to not promote our ProSomnus precision intraoral medical devices for uses outside of the FDA-cleared indications for use, known as off-label uses. We cannot, however, prevent a dental or medical professional from using our ProSomnus precision intraoral medical devices off-label when, in their independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury or other side effects to patients if physicians attempt to use our ProSomnus precision intraoral medical devices off-label. Furthermore, the use of our ProSomnus precision intraoral medical devices for indications other than those cleared by the FDA or cleared by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Given that we are aware that, notwithstanding our training guidelines, certain sleep dentists may use our ProSomnus precision intraoral medical devices off-label, there is a risk that we could face regulatory scrutiny as a result of such use. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violations that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

In addition, dentists may misuse our ProSomnus precision intraoral medical devices or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our ProSomnus precision intraoral medical devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizeable damage awards against us that may not be covered by insurance.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti- bribery and anti-kickback laws with respect to our activities outside the United States.

We distribute our products to locations within and outside the United States in Canada. Our business plan also anticipates distribution of our products outside of the United States and Canada. The U.S. Foreign Corrupt Practices Act, and other similar anti-bribery and anti-kickback laws and regulations, generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. As we expect to expand our international operations in the future, we will become increasingly subjected to these laws and regulations. We cannot assure you that we will be successful in preventing our agents from taking actions in violation of these laws or regulations. Such violations, or allegations of such violations, could disrupt our business and result in a material adverse effect on our financial condition, results of operations, and cash flows.

Risks Related to our Securities

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our Common Stock could be delisted from the Nasdaq.

The listing of our Common Stock on the Nasdaq Global Market (“Nasdaq”) is contingent on our compliance with the Nasdaq’s conditions for continued listing. We are currently not in compliance with Nasdaq listing requirements, specifically those that require us to maintain a minimum market value of publicly held shares of at least \$15.0 million and maintain a minimum market value of listed securities of at least \$50.0 million, and must regain compliance with such requirements on or prior to March 18, 2024 and February 12, 2024, respectively. If we are unable to regain such compliance, we will cease to be eligible to trade on Nasdaq and will likely be delisted by Nasdaq.

If we were to fail to meet a Nasdaq listing requirement, we may be subject to delisting by the Nasdaq. In the event our Common Stock is no longer listed for trading on Nasdaq, our trading volume and share price may decrease and we may experience further difficulties in raising capital, which could materially affect our operations and financial results. Further, delisting from the Nasdaq could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees and could also trigger various defaults under our financing arrangements and other outstanding agreements. Finally, delisting could make it harder for us to raise capital and sell securities. You may experience future dilution as a result of future equity offerings. In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock.

Concentration of ownership among ProSomnus’s existing executive officers, directors and their affiliates may prevent new investors from influencing significant corporate decisions.

Based on their holdings as of October 20, 2023, our directors and executive officers and their affiliates as a group will beneficially own approximately 7.7% of our outstanding Common Stock following receipt of stockholder approval. As a result, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, any amendment of our certificate of incorporation and any approval of significant corporate transactions. This control could have the effect of delaying or preventing a change of control or changes in management and will make the approval of certain transactions difficult or impossible without the support of these stockholders.

Sales of a substantial number of shares of our securities in the public market could cause the price of our securities to fall.

As of October 20, 2023, we had approximately 16,398,599 outstanding shares of Common Stock, and our warrants were exercisable into 6,512,087 shares of our Common Stock, each at \$11.50 per share.

In addition, as of October 20, 2023, we may issue the following additional shares of Common Stock:

- 2,411,283 shares of Common Stock reserved for issuance under the 2022 Equity Incentive Plan, which amount will increase by 3,588,717 shares if we obtain stockholder approval at the special meeting of stockholders to be held on December 6, 2023 (“Special Meeting”);

- 1,244,311 shares of our Common Stock issuable upon the exercise of outstanding options under the 2022 Equity Incentive Plan, with a weighted average exercise price of \$5.20 per share;
- 736,250 shares of our Common Stock issuable upon the vesting of outstanding restricted stock units granted under the 2022 Equity Incentive Plan;
- 3,000,000 shares of Common Stock issuable in satisfaction of our earnout obligations from the Business Combination; and
- 6,512,087 shares of Common Stock issuable upon exercise of our warrants and 3,704,760 shares of Common Stock issuable upon conversion of the Convertible Notes, which amounts increase to 8,218,150 shares of Common Stock and 26,889,449 shares of Common Stock once we obtain stockholder approval.

To the extent any or all such shares of Common Stock are issued, such additional shares of Common Stock will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market.

The registration statement filed on Form S-1 on November 1, 2023 covers the issuance of 5,424,524 shares of Common Stock issuable upon exercise of the Transaction Warrants and the offering and resale of an aggregate of 39,817,764 shares of Common Stock by the selling securityholders as listed on the Form S-1 filed on November 1, 2023. Such selling securityholders will determine the timing, pricing and rate at which they sell the shares being registered for resale into the public market. As of October 20, 2023, the shares being registered for resale, assuming all shares were outstanding following the conversion of the Convertible Notes, represented approximately 53.7% of the total number of shares outstanding, based on the number of shares of Common Stock outstanding as of October 20, 2023. Significant sales of shares of Common Stock may have negative pressure on the public trading price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our Common Stock and warrants.

Furthermore, pursuant to the registration rights agreement entered into in connection with the Business Combination, certain stockholders can demand that we register their registrable securities under certain circumstances and also have piggyback registration rights for these securities in connection with certain registrations of securities that we undertake. We also granted the certain registration rights to the investors party to the Securities Purchase Agreement.

We have filed and intend to maintain the registration statement previously filed on November 1, 2023 in order to facilitate registration of those sales. The registration of these securities will permit the exercise of such securities or the public resale of such securities, as applicable. The registration and availability of such a significant number of securities for trading in the public market may have an adverse effect on the market price of our securities.

There is no guarantee that any of our warrants will be in the money, and they may expire worthless.

As of November 1, 2023, we have 6,512,087 warrants to purchase Common Stock, which are exercisable at a price of \$11.50 per share, and 5,545,524 Transaction Warrants to purchase Common Stock, which, after obtaining stockholder approval, will be exercisable at a price of \$1.00 per shares, outstanding. The likelihood that the holders of the Transaction Warrants or the other warrants will exercise their respective warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the market price of our Common Stock, which is currently below the exercise price for our Transaction Warrants and our other warrants. If the market price of our Common Stock continues to be less than the exercise price, it is unlikely that holders will exercise such warrants, and therefore unlikely that we will receive any proceeds from the exercise of such warrants in the near future, or at all.

Our amended and restated certificate of incorporation grants our Board of Directors the power to issue additional shares of common and preferred stock and to designate series of preferred stock, all without stockholder approval.

As of September 30, 2023, we were authorized to issue 101,000,000 shares of capital stock, of which 100,000,000 shares are authorized as Common Stock and 1,000,000 shares are authorized as preferred stock, which amounts will be increased to 150,000,000 shares and 1,500,000 shares, respectively, if approved at the Special Meeting. Our Board of Directors, without any action by our stockholders, has and may again designate and issue shares of preferred stock in such series as it deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights, provided it is consistent with Delaware law.

The rights of holders of our preferred stock that have and may be issued could be superior to the rights of holders of Common Stock. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to

shares of the Common Stock. Further, any issuances of additional stock (common or preferred) will dilute the percentage of ownership interest of then current holders of our capital stock and may dilute the book value per share.

Specifically, pursuant to the Securities Purchase Agreement, we issued an aggregate of 10,426 shares of Series A Preferred Stock. With respect to any matter submitted to the vote of the holders of Common Stock, the holders of the Series A Preferred Stock are entitled to vote the whole number of votes equal to the number of shares of Common Stock into which such holder's Series A Preferred Stock would be convertible on the record date for the vote or consent of stockholders at a conversion price of \$1.04 per share of Common Stock rounded to the nearest whole share together, subject to certain limitations. The Series A Preferred Stock also ranks senior to the Common Stock and any other *pari passu* capital stock of the Company with respect to dividends, distributions and payments upon a liquidation event. Furthermore, the Series A Preferred Stock is convertible into Common Stock, subject to certain limitations, at a rate of 1,000 shares of Common Stock per one share of Series A Preferred Stock.

Servicing our existing and future debt, including the Convertible Notes, may require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness.

As of September 30, 2023, after giving effect to the in-kind interest payment on such date, we had approximately \$35.9 million aggregate principal amount of the Convertible Notes outstanding. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. In addition, any of our future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt.

In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry, and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and industry;
- place us at a disadvantage compared to our competitors who have less debt;
- limit our ability to borrow additional amounts to fund acquisitions, for working capital, and for other general corporate purposes; and
- make acquiring us less attractive or more difficult.

Any of these factors could harm our business, results of operations, and financial condition. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

We have not paid cash dividends on our capital stock, and we do not anticipate paying cash dividends in the foreseeable future.

We have never paid cash dividends on any of our capital stock and we currently intend to retain any future earnings to fund the growth of our business. Any determination to pay cash dividends in the future will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that the Board of Directors may deem relevant. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for the foreseeable future.

The trading price our securities is likely to be volatile, and you may not be able to sell our securities at or above the price you paid.

We expect the trading price of our Common Stock and Warrants to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include, but are not limited to:

- actual or anticipated fluctuations in operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock or the industry in general;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- operating and share price performance of other companies that investors deem comparable to us;
- our focus on long-term goals over short-term results;
- the timing and magnitude of our investments in the growth of our business;
- actual or anticipated changes in laws and regulations affecting our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- our ability to market new and enhanced products and technologies on a timely basis;
- sales of substantial amounts of the Common Stock by executive officers, directors or significant stockholders or the perception that such sales could occur;
- changes in our capital structure, including future issuances of securities or the incurrence of debt and the exercise or conversion of our outstanding warrants and shares of Series A Preferred Stock; and
- general economic, political and market conditions.

In addition, the stock market in general, and Nasdaq in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our securities, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our Common Stock or do not publish research or reports about us, the price and trading volume of our securities could decline.

The trading market for our Common Stock and Warrants will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our Common Stock and Warrants. The price of our Common Stock and Warrants could also decline if one or more equity research analysts downgrade their recommendations with respect to our Common Stock and Warrants, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of the company, we could lose visibility in the market, which in turn could cause the price of our securities to decline.

We may redeem your unexpired warrants other than the Transaction Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We may redeem outstanding warrants other than the Transaction Warrants prior to their exercise at a time that is disadvantageous to you, thereby significantly impairing the value of such warrants. We will have the ability to redeem outstanding warrants other than the Transaction Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the closing price of Common Stock equals or exceeds \$18.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending on the third trading day prior to the date on which a notice of redemption is sent to the warrant holders.

We will not redeem such warrants as described above unless a registration statement under the Securities Act covering the Common Stock issuable upon exercise of such warrants is effective and a current prospectus relating to the Common Stock is available throughout the 30-day redemption period. If and when such warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of such warrants could force you (i) to exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your warrants at the then-current market price when you might otherwise wish to hold your warrants, or (iii) to accept the

nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants.

The value received upon exercise of such warrants (1) may be less than the value the holders would have received if they had exercised their warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the warrants.

In the event we elect to redeem such warrants that are subject to redemption, we will mail the notice of redemption by first class mail, postage prepaid, not less than thirty days prior to the redemption date to the registered holders of the warrants to be redeemed at their last addresses as they appear on the registration books. Any notice mailed in such manner will be conclusively presumed to have been duly given whether or not the registered holder received such notice, and we are not required to provide any notice to the beneficial owners of such warrants. Additionally, while we are required to provide such notice of redemption, we are not separately required to, and do not currently intend to, notify any holders of when such warrants become eligible for redemption. If you do not exercise your warrants in connection with a redemption, including because you are unaware that such warrants are being redeemed, you would only receive the nominal redemption price for your warrants.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and bylaws, and in applicable law, could impair a takeover attempt.

Our amended and restated certificate of incorporation and bylaws afford certain rights and powers to our Board of Directors that could contribute to the delay or prevention of an acquisition that it deems undesirable, including:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- the ability of our Board of Directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the right of our Board of Directors to elect a director to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which may prevent stockholders from being able to fill vacancies on our Board of Directors;
- the requirement that a special meeting of stockholders may be called only by our Board of Directors or the chairman of the Board of Directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- the requirement for the affirmative vote of holders of at least 75% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend certain provisions of our amended and restated certificate of incorporation or to amend our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt.

We are also subject to Section 203 of the Delaware General Corporation Law and other provisions of Delaware law that limit the ability of stockholders in certain situations to effect certain business combinations. Any of the foregoing provisions and terms that has the effect of delaying or deterring a change in control could limit the opportunity for stockholders to receive a premium for their shares of Common Stock, and could also affect the price that some investors are willing to pay for the Common Stock.

Our amended and restated certificate of incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. These provisions will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Securities Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions

in the amended and restated certificate of incorporation. In addition, the amended and restated certificate of incorporation and bylaws will provide that, to the fullest extent permitted by law, claims made under the Securities Act must be brought in federal district court.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims and result in increased costs for investors to bring a claim. Alternatively, if a court were to find the choice of forum provision contained in the amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

General Risk Factors

Damage to our reputation or our brand could negatively impact our business, financial condition, and results of operations.

We must grow the value of our brand to be successful. We intend to develop a reputation based on the high quality of our products, services, and trained personnel, as well as of our particular culture and the experience of our patients with our recommended sleep dentists. If we do not make investments in areas such as marketing and advertising, as well as personnel training, the value of our brand may not increase or may be diminished. Any incident, real or perceived, regardless of merit or outcome, that adversely affects our brand, such as, but not limited to, patient disability or death due to malpractice or allegations of malpractice or failure to comply with federal, state, or local regulations, including allegations or perceptions of non-compliance or failure to comply with ethical and operational standards, could significantly reduce the value of our brand, expose us to negative publicity, and damage our overall business and reputation.

Our headquarters, digital medical device modeling processes, and other manufacturing processes are principally located in regions that are subject to earthquakes and other natural disasters.

Our corporate headquarters, sales, and marketing organization and manufacturing processes are in a single facility located in Pleasanton, California. Such location is in an earthquake zone and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where our facility is located, our ability to respond to customer inquiries or manufacture and ship our precision intraoral medical devices could be compromised which could result in our customers experiencing a significant delay in receiving their devices and a decrease in service levels for a period of time. Any such business interruption could materially and adversely affect our business, financial condition, and results of operations.

If payments from commercial or governmental payors are significantly delayed, reduced, or eliminated, our business, prospects, results of operations, and financial condition could be adversely affected.

We will depend upon revenue from sales of our ProSomnus precision intraoral medical devices, and in turn indirectly on reimbursement from third-party payors for such devices. The amount that dentists receive in payment for our ProSomnus precision intraoral medical devices may be adversely affected by factors we do not control, including federal or state regulatory or legislative changes, cost-containment decisions, and changes in reimbursement schedules of third-party payors. Any reduction or elimination of these payments could have a material adverse effect on our business, prospects, results of operations, and financial condition.

Additionally, the reimbursement process is complex and can involve lengthy delays. Also, third-party payors may reject, in whole or in part, requests for reimbursement based on determinations that certain amounts are not reimbursable under plan coverage, that services provided were not medically necessary, that additional supporting documentation is necessary, or for other reasons. Retroactive adjustments by third-party payors may be difficult or cost prohibitive to appeal, and such changes could materially reduce the actual amount received by patients or dentists. Delays and uncertainties in the reimbursement process may be out of our control and may adversely affect our business, prospects, results of operations, and financial condition.

Significant changes in our payor mix resulting from fluctuations in the types of patients seen by dentists could have a material adverse effect on our business, prospects, results of operations, and financial condition.

Our results may change from period to period due to fluctuations in dentists' payor mix. Payor mix refers to the relative amounts we receive from the mix of persons or entities that pay or reimburse dentists for healthcare services. Payment or reimbursement amounts

can vary from payor to payor, by geographic jurisdiction, and over time. A significant shift in our payor mix toward a higher percentage of self-pay or patients whose treatment is paid in whole or part by a governmental payor, could occur for reasons beyond our control and could lessen demand for our ProSomnus precision intraoral medical devices, which in turn could have a material adverse effect on our business, prospects, results of operations, and financial condition.

We may pursue acquisitions of complementary businesses or technologies, which could divert the attention of management and which may not be integrated successfully into our existing business.

We may pursue acquisitions or licenses of technology to, among other things, expand the scope of products and services we provide. We cannot guarantee that we will identify suitable acquisition candidates, that acquisitions will be completed on acceptable terms, or that we will be able to successfully integrate the operations of any acquired business into our existing business. The acquisition and integration of another business or technology would divert management attention from other business activities, including our core business. In addition, we may borrow money or issue capital stock to finance acquisitions. Such borrowings might not be available on terms as favorable to us as our current borrowing terms and may increase our leverage, and the issuance of capital stock could dilute the interests of our stockholders.

Our business is seasonal, which impacts our results of operations.

We believe that the patient volumes of sleep medicine healthcare will be sensitive to seasonal fluctuations in urgent care and primary care activity. Typically, winter months see a higher occurrence of influenza, bronchitis, pneumonia, and similar illnesses; however, the timing and severity of these outbreaks vary dramatically.

Additionally, as consumers shift toward high deductible insurance plans, they are responsible for a greater percentage of their bill, particularly in the early months of the year before other healthcare spending has occurred, which may lead to lower than expected patient volume or an increase in bad debt expense during that period. Our quarterly operating results may fluctuate significantly in the future depending on these and other factors.

We depend on certain key personnel.

We substantially rely on the efforts of our current senior management, including our Chief Executive Officer, Chief Financial Officer and our Chief Technology Officer. Our business would be impeded or harmed if we were to lose their services. In addition, if we are unable to attract, train, and retain highly skilled technical, managerial, product development, sales, and marketing personnel, we may be at a competitive disadvantage and unable to develop new products or increase revenue. The failure to attract, train, retain and effectively manage employees could negatively impact our research and development, sales and marketing and reimbursement efforts. In particular, the loss of sales personnel could lead to lost sales opportunities as it can take several months to hire and train replacement sales personnel. Uncertainty created by turnover of key employees could adversely affect our business.

Members of our Board of Directors will have other business interests and obligations to other entities.

None of our independent directors will be required to manage our business as their sole and exclusive function and they may have other business interests and may engage in other activities in addition to those relating to us, provided that such activities do not compete with the business of our company or otherwise breach their agreements with us. We are dependent on our directors and executive officers to successfully operate our company. Their other business interests and activities could divert time and attention from operating our business.

We will need to carefully manage our expanding operations to achieve sustainable growth.

To achieve increased revenue levels, market our products internationally, complete clinical studies and develop future products, we believe that we will be required to periodically expand our operations, particularly in the areas of sales and marketing, clinical research, reimbursement, research and development, manufacturing, and quality assurance. As we expand our operations in these areas, management will face new and increased responsibilities. To accommodate any growth and compete effectively, we must continue to upgrade and improve our information systems, procedures, and controls across our business, as well as expand, train, motivate, and manage our workforce. Our future success will depend significantly on the ability of our current and future management to operate effectively. Our personnel, systems, procedures, and controls may not be adequate to support our future operations. If we are unable to

effectively manage our expected growth, this could have a material adverse effect on our business, financial condition, and results of operations.

Downturns or volatility in general economic conditions could have a material adverse effect on our business, financial condition, results of operations and liquidity.

Our revenues and profitability depend significantly on general economic conditions and the demand for our products in the markets in which our customers and their patients are located. Weaknesses in the global economy and financial markets, including the current weaknesses resulting from the ongoing COVID-19 pandemic or geopolitical instability, could lead to lower demand for our products. A decline in patient or customer demand can affect the need that customers have for our products, and the money or insurance available to pay for our devices. Any further adverse changes in economic conditions, including any recession, economic slowdown or disruption of credit markets, or the outbreak of war or conflict, may also lead to lower demand for our products. Volatile and uncertain economic conditions can make it difficult to accurately forecast and plan future business activities.

All of these factors related to general economic conditions, which are beyond our control, could adversely impact our business, financial condition, results of operations and liquidity.

Our management team has limited experience managing a public company.

Most members of our management team have limited or no experience managing a publicly traded company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that govern public companies. There are significant obligations that we will be subject to relating to reporting, procedures and internal controls, and our management team may not successfully or efficiently manage our transition to being a public company. These new obligations and added scrutiny will require significant attention from our management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, operating results and financial condition.

Inadequate internal controls could result in inaccurate financial reporting.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, our stockholders could lose confidence in our financial reporting, which could adversely affect results of our business and our enterprise value.

We will need to undertake significant efforts to strengthen our processes and systems and adapt them to changes as our business evolves (including with respect to becoming a publicly traded company). This continuous process of maintaining and adapting our internal controls is expensive and time-consuming, and requires significant management attention. We cannot be certain that our internal control measures will, in the future, provide adequate control over our financial processes and reporting. Furthermore, as our business evolves and if we expand through acquisitions of other companies or make significant investments in other companies or enter into joint development and similar arrangements, our internal controls may become more complex and we will require significantly more resources to ensure our internal controls remain effective. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. If we or our independent registered public accounting firm identify material weaknesses, the disclosure of that fact, even if quickly remediated, could reduce the market's confidence in our financial statements and harm our enterprise value.

Our actual operating results may differ significantly from our guidance.

From time to time, we provide forward looking estimates regarding our future performance that represent our management's estimates as of a point in time. These forward-looking statements are based on projections prepared by our management. These projections are not prepared with a view toward compliance with published guidelines of the American Institute of Certified Public Accountants, and neither our independent registered public accountants nor any other independent expert or outside party compiles or examines the projections and, accordingly, no such person expresses any opinion or any other form of assurance on our projections.

Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions and conditions, some of which will change. The principal

reason that we provide forward looking information is to provide a basis for our management to discuss our business outlook with stockholders. Forward-looking statements are necessarily speculative in nature, and it can be expected that some or all of the assumptions of our forward-looking statements will not materialize or will vary significantly from actual results. Accordingly, our forward-looking statements are only an estimate of what management believes is realizable as of the date of release. Actual results will vary from our forward-looking statements and the variations may be material. In light of the foregoing, investors are urged not to rely upon, or otherwise consider, our guidance in making investment decisions.

We qualify as an “emerging growth company” and a “smaller reporting company” within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as an “emerging growth company” as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (a) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (b) the exemptions from say-on-pay, say-on-frequency and say-on- golden parachute voting requirements, and (c) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of Common Stock that are held by non-affiliates exceeds \$700.0 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of \$1.235 billion or more during such fiscal year (as indexed for inflation), (iii) the date on which we have issued more than \$1 billion in non-convertible debt in the prior three-year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of Common Stock in Lakeshore’s initial public offering of units, consummated on June 15, 2021. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as it is an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to opt out of such extended transition period and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Investors may find our securities less attractive because we will rely on these exemptions, which may result in a less active trading market for our securities.

Additionally, we qualify as a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We expect to remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Common Stock held by non-affiliates exceeds \$250,000,000 as of the prior June 30, or (ii) our annual revenues exceeded \$100,000,000 during such completed fiscal year and the market value of our Common Stock held by non-affiliates exceeds \$700,000,000 as of the prior June 30. To the extent we take advantage of such reduced disclosure obligations, comparison of our financial statements with other public companies may be difficult or impossible.

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

None.

Item 6. Exhibits

See Exhibit Index.

EXHIBIT INDEX

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation of ProSomnus, Inc. (previously filed as Exhibit 3.1 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).</u>
3.2	<u>Amended and Restated Bylaws of ProSomnus, Inc. (previously filed as Exhibit 3.2 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).</u>
3.3	<u>Certificate of Designations (previously filed as Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).</u>
4.1	<u>Second Supplemental Indenture, dated as of September 20, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (previously filed as Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).</u>
4.2	<u>Second Supplemental Indenture, dated as of September 20, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (previously filed as Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).</u>
4.3	<u>Indenture, dated as of October 11, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (previously filed as Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).</u>
4.4	<u>Form of Senior Secured Convertible Exchange Note due December 6, 2025 (included in Exhibit 4.3).</u>
4.5	<u>Indenture, dated as of October 11, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (previously filed as Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).</u>
4.6	<u>Form of Subordinated Secured Convertible Exchange Note due April 6, 2026 (included in Exhibit 4.5).</u>
10.1	<u>Form of Securities Purchase Agreement, dated as of September 20, 2023, by and among ProSomnus, Inc. and the investors named therein (previously filed as Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).</u>
10.2	<u>Senior Security Agreement, dated as of October 11, 2023, by and among ProSomnus, Inc., the subsidiaries of ProSomnus, Inc., from time to time party thereto, and Wilmington Trust, National Association, as collateral agent (previously filed as Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).</u>
10.3	<u>Subordinated Security Agreement, dated as of October 11, 2023, by and among ProSomnus, Inc., the subsidiaries of ProSomnus, Inc., from time to time party thereto, and Wilmington Trust, National Association, as collateral agent (previously filed as Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).</u>
10.4	<u>Form of Restricted Stock Unit Award (previously filed as Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 19, 2023).</u>

[Table of Contents](#)

31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	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
101.SCH†	XBRL Taxonomy Extension Schema Document
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Filed herewith.

* Furnished herewith

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, duly authorized.

Date: November 14, 2023

PROSOMNUS, INC.

By: /s/ Brian Dow
Name: Brian Dow
Title: Chief Financial Officer
(Principal Financial Officer)

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

I, Len Liptak, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ProSomnus, 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.

Dated: November 14, 2023

By: /s/ Len Liptak

Name: Len Liptak

Title: Chief Executive Officer

(Principal Executive Officer)

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

I, Brian Dow, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ProSomnus, 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.

Dated: November 14, 2023

By: /s/ Brian Dow

Name: Brian Dow

Title: Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of ProSomnus, Inc. (the "Company") hereby certifies, to the best of my knowledge, that:

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2023

By: /s/ Len Liptak

Name: Len Liptak

Title: Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of ProSomnus, Inc. (the “Company”) hereby certifies, to the best of my knowledge, that:

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2023

By: /s/ Brian Dow

Name: Brian Dow

Title: Chief Financial Officer
(Principal Financial and Accounting Officer)
