

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 26, 2024

ProSomnus, Inc.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-41567</u> (Commission File Number)	<u>88-2978216</u> (I.R.S. Employer Identification No.)
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5675 Gibraltar Drive
Pleasanton, California 94588
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: (844) 537-5337

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each 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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On March 26, 2024, ProSomnus, Inc. (“ProSomnus” or the “Company”) issued a press release announcing our financial results for the three- and twelve-months ended December 31, 2023. A copy of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that section and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by ProSomnus, Inc. dated March 26, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

PROSOMNUS, INC.

Date: March 26, 2024

By: /s/ Brian B. Dow

Name: Brian B. Dow

Title: Chief Financial Officer

ProSomnus Reports Record Fourth Quarter and Fiscal Year 2023 Financial Results

PLEASANTON, Calif., (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: OSA), the leading non-CPAP therapy™ for the treatment of Obstructive Sleep Apnea (OSA), today announced financial results for the fourth quarter and year ended December 31, 2023.

Recent Business Highlights

- Generated record revenues of \$7.8 million for the fourth quarter and \$27.7 million for the fiscal year 2023, a 35% increase compared to \$5.8 million for the fourth quarter 2022 and 43% increase compared to \$19.4 million for fiscal year 2022. The quarter marked the eighth (8th) sequential quarter of record revenues.
- Continued focus on implementing reductions in operating expenses. Operating expenses, excluding cost of revenue, decreased over 8% compared to operating expenses reported for the second quarter of 2024 and decreased nearly 19% as a percentage of revenue over the same period.
- Initiated comprehensive review of financing and strategic alternatives to strengthen the balance sheet and fund future growth initiatives.
- Demonstrated technical feasibility of the Company's Next Generation Remote Patient Monitoring (RPM) device for Obstructive Sleep Apnea (OSA). Data from a recently completed pilot study demonstrated that an oximeter embedded in a precision intraoral medical device can accurately, safely, and continuously monitor SpO₂.
- Submitted 510(k) Premarket Notification to U.S. Food and Drug Administration for severe indication label expansion. Currently in substantive review phase.
- Maintained >98% on time delivery and patient and provider satisfaction.
- Secured ISO 13485:2016 certification of the Company's quality management system

“I am thrilled to announce another record revenue quarter and fiscal year for ProSomnus, as we establish the ProSomnus EVO® precision intraoral technology as a truly differentiated therapy for Obstructive Sleep Apnea,” said Len Liptak, Chief Executive Officer. “The team worked tremendously towards executing on our strategic deliverables, and achieved a record number of procedures in both Q4 and the full year. 2023 was an impactful year, as we continued to generate and share strong clinical data supporting the use of ProSomnus precision oral appliance therapy as a first line therapy for Obstructive Sleep Apnea, advanced enrollment in the Severe Obstructive Sleep Apnea study, and prepared a robust dossier to support a premarket submission to the FDA earlier this year for label expansion to include severe OSA. We continued to fine-tune our operations in an effort to progress towards cash flow breakeven while maintaining strong top line growth. In all, it was a tremendous year of achievements as we advance our mission to position ProSomnus as the leading non-CPAP therapy for Obstructive Sleep Apnea. I am proud of the 2023 results, and I look forward to building upon this momentum during 2024.”

Financial Results for the Fourth Quarter and Year Ended December 31, 2023

Revenues increased to \$7.8 million for the fourth quarter ended December 31, 2023. This reflects an increase of \$0.8 million, or 11%, and \$2.0 million, or 35%, compared to the quarters ended September 2023 and December 2022, respectively. Revenue for the full year 2023 increased to \$27.7 million, an increase of \$8.3 million, or 43%, compared to the year ended December 31, 2022. This increase was primarily driven by increased adoption of our precision devices, increased sales and marketing investments, and mix shift to the EVO Product, all of which contributed to increased unit volumes.

Cost of revenue totaled \$4.1 million for the fourth quarter ended December 31, 2023, representing 53% of revenue. This reflects an increase of \$0.6 million, or 15%, and \$1.4 million, or 54%, compared to the quarters ended September 2023 and December 2022, respectively. For the full year 2023 cost of revenue totaled \$13.6 million, representing 49% of revenue, an increase of \$4.5 million, or 49%, compared to \$9.1 million, or 47% of revenue, for the year ended December 31, 2022. The increase was primarily due to product costs associated with higher sales volume of our devices and increased overhead stemming from our move into our new manufacturing facility during early 2023.

Sales and marketing expenses totaled \$3.4 million for the fourth quarter ended December 31, 2023. Relative to the quarter ended June 30, 2023, the commencement of our expense reduction initiative, sales and marketing has decreased 6% and as percentage of revenue has decreased from 53% to 43% for the quarters ended December 31, 2023 and June 30, 2023, respectively. Fourth quarter 2023 sales and marketing expense reflects a modest increase compared to the quarter ended September 2023, and an increase of \$1.0 million, or 40%, compared to the quarter ended December 2022. Sales and marketing expenses for the full year 2023 totaled \$13.1 million, an increase of \$4.2 million, or 48%, compared to the year ended December 31, 2022. This year-over-year increase reflects an increase in personnel and consulting-related expenses of \$2.7 million due to expansion of the sales team during mid-2023, distribution, marketing events, and advertising expenses of \$1.2 million, and commissions paid on higher revenues.

General and administrative expenses totaled \$4.0 million for the quarter ended December 31, 2023. Relative to the quarter ended June 30, 2023, general and administrative expenses decreased 11% and as percentage of revenue has decreased from 65% to 51% for the quarters ended December 31, 2023 and June 30, 2023, respectively. Fourth quarter 2023 general and administrative expenses reflect an increase of \$0.5 million, or 16%, compared to the quarter ended September 2023, and a decrease of \$1.7 million, or 30%, compared to the quarter ended December 2022. For the full year 2023 general and administrative expenses totaled \$15.2 million, an increase of \$5.3 million, or 54%, compared to \$9.9 million for the year ended December 31, 2022. This increase was driven primarily by \$2.9 million increase in costs that scale with top line and production growth including credit card fees, utilities, rent and depreciation associated with the new manufacturing facility, and public company expenses including \$2.5 million increase in professional services, \$1.3 million increase in personnel costs, and \$1.0 million in insurance, partially offset by \$1.4 million decrease in stock-based compensation.

Research and development expenses totaled \$1.4 million for the quarter ended December 31, 2023. Relative to the quarter ended June 30, 2023, the commencement of our expense reduction initiative, research and development expenses remained consistent and as percentage of revenue has decreased from 20% to 17% for the quarters ended December 31, 2023 and June 30, 2023, respectively. Fourth quarter 2023 reflects an increase of \$0.3 million, or 31.4%, and \$0.3 million, or 28% compared to the quarters ended September 2023 and December 2022, respectively. For the full year 2023 research and development expenses totaled \$4.8 million, an increase of \$1.8 million, or 61%, compared to the year ended December 31, 2022. This increase was primarily driven by an increase in expenses associated with the ongoing development of the RPMO₂, the Front Line OSA Therapy ("FLOSAT") clinical study and costs associated with preparing the 510(k) Premarket Notification to U.S. Food and Drug Administration for the severe indication label expansion.

Other income (expense) is comprised of interest expense and accounting charges associated with changes in fair values of certain assets and liabilities and charges associated with financings and debt restructuring. Total other expense for the year ended December 31, 2023 aggregated to \$5.0 million compared to total other income of \$4.3 million for the year ended December 31, 2022. The other income resulting from the valuation changes in certain of our liabilities reflect the price decline of our publicly traded stock which is a significant input into the fair value valuation assumptions for the liabilities revalued. This other income was offset during 2023 by a loss on debt restructuring associated with changes in the terms of certain of our senior and subordinate indentures as part of our September 2023 financing transactions. Interest expense reflects the interest on our senior and subordinate indentures and equipment financing liabilities.

Cash and restricted cash at December 31, 2023 totaled \$7.1M, reflecting a decrease of \$4.9 million from the \$12.0 million reported at September 30, 2023. The decrease noted includes approximately \$1.0 million of cash used to renew the Company's insurance policies during December 2023.

Conference Call and Webcast Information

Interested parties may register for the conference call at 1:30 pm PT / 4:30 pm ET, today March 26, 2024 using the following link: [OSA Q4 2024 Financial Results Call](#). Alternatively, you may access the live webcast of the conference call by using the following link: [OSA Q4 2024 Webcast](#). The links will also be posted in the Investor Relations section of the ProSomnus website at [News & Events](#).

About ProSomnus

ProSomnus (NASDAQ: [OSA](#)) is the leading non-CPAP therapy for the treatment of Obstructive Sleep Apnea, a serious medical disease affecting over 1 billion people worldwide, that is associated with comorbidities including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus intraoral medical devices are engineered to precisely track the treatment plan and anatomy for each patient. Non-invasive, patient preferred and easy to use, ProSomnus devices have demonstrated excellent efficacy, safety, adherence, and overall outcomes in a growing body of clinical investigations. ProSomnus precision intraoral devices are FDA-cleared, patented, and covered by commercial medical insurance, Medicare, TRICARE and many Government-sponsored healthcare plans around the world, representing over 200 million covered lives. To learn more, visit www.ProSomnus.com.

Important Notice Regarding Forward-Looking Statements

This Press Release contains certain "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements about the Company's review of potential financing and strategic alternatives, the Company's research and development efforts, the Company's prospects for 2024, the Company's mission of becoming the leader non-CPAP therapy for Obstructive Sleep Apnea and the Company's ability to fine tune its operations, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements, although not all forward-looking statements contain these or similar identifying words.

These forward-looking statements are not guarantees of future performance and are subject to various risks and uncertainties, assumptions (including assumptions about general economic, market, industry and operational factors), known or unknown, which could cause the actual results to vary materially from those indicated or anticipated. Such risks and uncertainties include, but are not limited to: ProSomnus's ability to continue as a going concern; ProSomnus's ability raise additional capital to fund its business on acceptable terms or at all; ProSomnus's ability to regain compliance with the covenants under its convertible notes; ProSomnus's ability to negotiate and consummate a financing or other strategic transaction; changes in the competitive industries in which the Company operates and variations in operating performance across competitors; changes in laws and regulations affecting ProSomnus's business; the risk of downturns in the market and ProSomnus's industry; risks related to the uncertainty of the projected financial information with respect to ProSomnus; risks related to ProSomnus's limited operating history and history of losses; the timing of expected business milestones; ProSomnus's ability to implement its business plan and scale its business, which includes the recruitment of healthcare professionals to prescribe and dentists to deliver ProSomnus oral devices; the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; the potential financial benefits to dentists and other healthcare professionals from treating patients with ProSomnus oral devices and using ProSomnus's monitoring tools; ProSomnus's potential profit margin from sales of ProSomnus oral devices; ProSomnus's ability to properly train dentists in the use of the ProSomnus oral devices and other services it offers in their dental practices; ProSomnus's ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; ProSomnus's ability to expand internationally; the viability of ProSomnus's intellectual property and intellectual property created in the future; acceptance by the marketplace of the products and services that ProSomnus markets; 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; the extent of patient reimbursement by medical insurance in the United States and internationally; and the outcome of any legal proceedings that may be instituted against the Company. A further list and description of risks and uncertainties can be found in the most recent filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements relate only to the date they were made, and the Company undertakes no obligation to update forward-looking statements to reflect events or circumstances after the date they were made except as required by law or applicable regulation.

PROSOMNUS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands)

	Three Month Period Ended			Three Month Period Ended			
	December 31	September 30	December 31	December 31, 2023 vs. September 30, 2023		December 31, 2023 vs 2022	
	2023	2023	2022	(\$)	(%)	(\$)	(%)
Revenue	\$ 7,838	\$ 7,071	\$ 5,792	\$ 767	10.8%	\$ 2,046	35.3%
Operating expenses							
Cost of revenue	4,133	3,580	2,687	553	15.4%	1,446	53.8%
Sales and marketing	3,378	3,240	2,415	138	4.3%	963	39.9%
Research and development	1,367	1,040	1,065	327	31.4%	302	28.4%
General and administrative	3,970	3,427	5,675	543	15.8%	(1,705)	-30.0%
Total operating expenses	12,848	11,287	11,842	1,561	13.8%	1,006	8.5%
Loss from operations	(5,010)	(4,216)	(6,050)	(794)	18.8%	1,040	-17.2%
Other income (expense)							
Interest expense	(1,481)	(1,489)	(2,405)	8	-0.5%	924	-38.4%
Change in fair value of earnout liability	110	3,880	9,260	(3,770)	-97.2%	(9,150)	-98.8%
Change in fair value of debt	258	3,700	553	(3,442)	-93.0%	(295)	-53.3%
Change in fair value of warrant liability	39	593	3,255	(554)	-93.4%	(3,216)	-98.8%
Loss on extinguishment of debt	(707)	(9,743)	(2,405)	9,036	-92.7%	1,698	-70.6%
Other	(78)	(3,964)	-	3,886	-98.0%	(78)	-
Total other income (expense)	(1,859)	(7,023)	8,258	5,164	-73.5%	(10,117)	-122.5%
Net loss	\$ (6,869)	\$ (11,239)	\$ 2,208	\$ 4,370	-38.9%	\$ (9,077)	-411.1%

	Year Ended		Year Ended	
	December 31	December 31	December 31, 2023 vs 2022	
	2023	2022	(\$)	(%)
Revenue	\$ 27,652	\$ 19,393	\$ 8,259	42.6%
Operating expenses				
Cost of revenue	13,641	9,127	4,514	49%
Sales and marketing	13,085	8,865	4,220	47.6%
Research and development	4,802	2,981	1,821	61.1%
General and administrative	15,230	9,895	5,335	53.9%
Total operating expenses	46,758	30,868	15,890	51.5%
Loss from operations	(19,106)	(11,475)	(7,631)	66.5%
Other income (expense)				
Interest expense	(5,382)	(6,120)	738	-12.1%
Change in fair value of earnout liability	12,190	9,260	2,930	31.6%
Change in fair value of debt	1,328	553	775	140.1%
Change in fair value of warrant liability	1,896	3,235	(1,339)	-41.4%
Loss on extinguishment of debt	(10,450)	(2,598)	(7,852)	302.2%
Other	(4,571)	-	(4,571)	-
Total other income (expense)	(4,989)	4,330	(9,319)	-215.2%
Net loss	\$ (24,095)	\$ (7,145)	\$ (16,950)	237.2%

PROSOMNUS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash, restricted cash and cash equivalents	\$ 7,063	\$ 15,916
Accounts receivable, net	3,839	2,843
Inventory	2,039	640
Prepaid expenses and other current assets	1,369	1,851
Total current assets	14,310	21,250
Property and equipment, net	3,358	2,404
Finance lease right-of-use assets	3,265	3,650
Operating lease right-of-use assets	5,069	5,633
Other assets	285	263
Total assets	\$ 26,287	\$ 33,200
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,047	\$ 2,102
Accrued expenses and other current liabilities	6,756	3,706
Equipment financing obligation	57	59
Finance lease liabilities	1,052	1,009
Operating lease liabilities	304	215
Senior Convertible Notes at fair value, current portion	2,125	—
Total current liabilities	14,341	7,091
Equipment financing obligation, net of current portion	129	186
Finance lease liabilities, net of current portion	2,009	2,081
Operating lease liabilities, net of current portion	5,221	5,526
Senior Convertible Notes at fair value, net of current portion	12,152	13,651
Subordinated Convertible Notes at fair value	18,320	10,356
Earnout and warrant liability	716	14,802
Total liabilities	52,888	53,693
Commitments and contingencies		
Redeemable convertible preferred stock:		
	11,555	—
Stockholders' deficit:		
Common Stock	2	2
Additional paid-in capital	196,731	190,299
Accumulated deficit	-234,889	-210,794
Total stockholders' deficit	-38,156	-20,493
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 26,287	\$ 33,200

Investor Contact

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