

**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): May 9, 2023

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

Delaware
(State or other jurisdiction
of incorporation)

001-41567
(Commission
File Number)

88-2978216
(I.R.S. Employer
Identification No.)

5675 Gibraltar Avenue
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))

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 May 9, 2023, ProSomnus, Inc. (“ProSomnus”) issued a press release announcing its financial results for the quarter ended March 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 May 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

PROSOMNUS, INC.

Date: May 9, 2023

By: /s/ Brian B. Dow

Name: Brian B. Dow

Title: Chief Financial Officer

ProSomnus Reports First Quarter 2023 Financial Results

PLEASANTON, Calif., May 9, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (“the Company” or “ProSomnus”) (NASDAQ: [OSA](#)), a pioneer in precision medical devices for the treatment of Obstructive Sleep Apnea (OSA), today announced financial results for the first quarter ended March 31, 2023.

Recent Business Highlights

- Generated year-over year revenue growth of 55% reflecting revenues of \$5.8 million for the first quarter compared to \$3.7 million during the first quarter of 2022, and in line with strong revenues in the fourth quarter of 2022.
- Continued traction on strategic growth initiatives, including direct sales team expansion in the U.S. and Europe, advancing our next generation device with remote patient monitoring capability toward commercial introduction during late 2023 and the continued generation of clinical data.
- Commenced enrollment in the Severe Obstructive Sleep Apnea (SOS) labeling expansion study, with all five centers activated and on track to complete enrollment in 2023.
- Successfully moved to our new headquarters and manufacturing center of excellence. The move quintupled our potential manufacturing capacity, positioning ProSomnus to be able to meet the rapidly growing demand for the company’s precision intraoral medical devices.
- Expanded the Company’s patent portfolio by securing two additional patents covering its digital manufacturing and iterative titration technologies.

“ProSomnus delivered strong operational results and made healthy strategic progress during our first full quarter as a public company,” said Len Liptak, Chief Executive Officer. “ProSomnus generated record revenues for the quarter, underscored by year over year revenue growth that exceeded 50%. These results reflect the growing acceptance of our precision medical devices as a solution for the millions suffering from OSA, driven by investments in our direct sales and scientific marketing capabilities, the robust data supporting precision oral appliance therapy, and the expansion of our digital manufacturing operations.”

Financial Results for the First Quarter of 2023

Revenue for the three-month period and year ended March 31, 2023 totaled \$5.8 million, an increase of 55% over \$3.7 million in the first quarter of 2022. Seasonal strength during the fourth quarter historically has resulted in sequential quarter-over-quarter softness in results, however the strong revenue performance of the fourth quarter 2022 continued during the first quarter 2023 as revenues of \$5.8 million were reported for both periods. The year-over-year increase was primarily driven by increased unit volume due to increased sales and marketing investments and mix shift to the new EVO Products.

Gross margin finished at 53% for the three-month period ended March 31, 2023, consistent with the 54% for the three-month period ended December 31, 2022. The decrease in gross margin compared to 58% for the three-month period ended March 31, 2022, reflects the impact of our strategic investment in the Company’s new manufacturing facility, which was completed during the first quarter of 2023 and prepares the company for future growth. Cost of revenues is driven principally by cost of materials combined with direct and indirect labor and facilities overhead. We expect that these modest period fluctuations will mitigate with the scale of additional volume.

Sales and marketing expenses increased by \$0.7 million, or 33%, for the three month ended March 31, 2023, compared to the same period in the prior year and \$0.4 million, or 17%, compared to the prior quarter. This increase was driven by additional direct sales personnel reflecting the planned investment in commercial resources that began in late 2022.

Research and development expenses increased by \$0.5 million, or 83%, for the three-months period ended March 31, 2023, compared to same period in the prior year and consistent with the prior quarter. R&D expenses reflect the investments being made in developing the next generation remote patient monitoring device, execution of the FLOSAT head-to-head comparison study, and commencement of the label expansion SOS study.

General and administrative expenses increased by \$2.0 million for the three months ended March 31, 2023, compared to the three-month period ended March 31, 2022, and decreased \$2.0 million compared to the prior quarter. The first quarter of 2023 reflects the first quarter of public company operations including an increase in professional and consulting services to facilitate the transition combined with continuing expenses related to the consummation of the business combination during December 2022. The fourth quarter included several transaction-related charges including material stock-based compensation charges that are not expected to recur or, if recurring, are expected to recur at materially reduced levels.

Total other income (expense) totaled an expense of \$2.7 million for the three-month period ended March 31, 2023, compared to an expense of \$1.1 million for the prior year and income of \$8.3 million for the prior quarter. Interest expenses increased modestly to \$1.2 million during the first quarter, compared to the same quarter in the prior year and the prior quarter, reflecting the first full quarter of interest on debt entered into during December 2022. Liabilities recorded in connection with the business combination are recorded at fair value with changes in fair value reported as elements of other income (expense).

On March 31, 2023, cash and cash equivalents totaled \$11.6 million.

Conference Call and Webcast Information

The Company will host a conference call to discuss its first quarter 2023 financial results today, May 9, 2023, at 4:30 pm ET. Interested parties may register for the conference call using the following link: [ProSomnus Q1 Earnings Registration Link](#). You may access the live webcast of the conference call by using the following link: [ProSomnus Q1 Earnings Call](#). The link will also be posted in the Investor Relations section of the ProSomnus website at [News & Events](#).

About ProSomnus

ProSomnus (NASDAQ: OSA) precision intraoral medical devices offer effective, economical, and patient-preferred treatment for patients suffering from Obstructive Sleep Apnea (OSA). ProSomnus is the first manufacturer of mass-customized Precision Oral Appliance Therapy (OAT) devices to treat OSA, which affects over 74 million people in North America and is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus's patented, FDA-cleared devices are a less invasive and more comfortable alternative to Continuous Positive Airway Pressure (CPAP) therapy, and lead to effective and patient-preferred outcomes. A growing body of research, including studies published by the *Journal of Clinical Sleep Medicine* and *Military Medicine*, suggests ProSomnus's Precision OAT devices are an effective treatment for mild to moderate OSA. Additional clinical research has shown that ProSomnus's Precision OAT devices mitigate many of the side effects associated with alternative treatments and improve economics for payers and providers. With more than 200,000 devices delivered, ProSomnus's devices are the most prescribed Precision OAT in the U.S. ProSomnus's FDA-cleared devices are authorized by the Department of Defense and the U.S. Army, and are often covered by medical insurance, Medicare, and social health programs in key international markets. 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 Section 27A of the Securities Act of 1933 and Section 21E the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements regarding ProSomnus's labeling expansion, its future growth and expenses, and the growing markets for its devices, are forward-looking statements. 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. 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. 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: (i) risk related to being unable to comply with its debt covenants or successfully renegotiate such covenants; (ii) the risk of potential future significant dilution to stockholders resulting from lender conversions under the convertible debt financing; (iii) uncertainty of the projected financial information with respect to ProSomnus; (iv) ProSomnus's limited operating history and history of losses; (v) the roll-out of ProSomnus's business and the timing of expected business milestones; (vi) the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; (vii) expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; (viii) ProSomnus's ability to maintain and grow its profit margin from sales of ProSomnus oral devices; (ix) ProSomnus's ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; (x) ProSomnus's ability to expand internationally; (xi) the viability of ProSomnus's intellectual property and intellectual property created in the future; (xii) 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; (xiii) the risk of downturns in the market and ProSomnus's industry including, but not limited to, as a result of the COVID-19 pandemic; and (xiv) the outcome of any legal proceedings that may be instituted against ProSomnus. A further list and description of risks and uncertainties can be found in ProSomnus's annual reports on Form 10-K filed with the Securities and Exchange Commission (the "SEC") any subsequently filed quarterly reports on Form 10-Q, and other documents that the parties may file or furnish with the SEC, which you are encouraged to read. 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. Forward-looking statements do not represent our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three-month period ended		
	March 31, 2023	December 31, 2022	March 31, 2022
Revenue	\$ 5,808,380	\$ 5,792,312	\$ 3,743,143
Cost of revenue	2,756,631	2,686,863	1,578,496
Gross profit	3,051,749	3,105,449	2,164,647
Operating expenses			
Sales and marketing	2,824,048	2,415,155	2,117,419
Research and development	1,018,969	1,065,750	557,633
General and administrative	3,353,007	5,674,961	1,353,735
Total operating expenses	7,196,024	9,155,866	4,028,787
Loss from operations	(4,144,275)	(6,050,417)	(1,864,140)
Other income (expense)			
Interest expense	(1,171,810)	(2,405,029)	(1,095,837)
Change in fair value of earnout liability	1,500,000	9,260,000	-
Change in fair value of debt	(1,827,000)	553,235	-
Change in fair value of warrant liability	(842,559)	3,255,342	(20,756)
Other	(406,527)	-	-
Loss on extinguishment of debt	-	(2,405,111)	-
Total other income (expense)	(2,747,896)	8,258,437	(1,116,593)
Net loss	\$ (6,892,171)	\$ 2,208,020	\$ (2,980,733)

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,560,319	\$ 15,916,141
Accounts receivable, net	2,662,752	2,843,148
Inventory	758,188	639,945
Prepaid expenses and other current assets	1,571,197	1,846,870
Total current assets	16,552,456	21,246,104
Property and equipment, net	2,994,769	2,404,402
Right-of-use assets, net	8,775,016	9,283,222
Other assets	262,913	262,913
Total assets	<u>\$ 28,585,154</u>	<u>\$ 33,196,641</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,309,656	\$ 2,101,572
Accrued Expenses	4,906,746	3,706,094
Equipment financing obligation	57,839	58,973
Finance lease liabilities	898,027	1,008,587
Operating lease liabilities	329,767	215,043
Total current liabilities	7,502,035	7,090,269
Equipment financing obligation, net of current portion	171,984	185,645
Finance lease liabilities, net of current portion	1,917,877	2,081,410
Operating lease liabilities, net of current portion	5,452,282	5,525,562
Senior Convertible notes	14,478,000	13,651,000
Subordinated Convertible note	12,079,380	10,355,681
Earnout Liability	11,310,000	12,810,000
Warrant liability	2,834,062	1,991,503
Total liabilities	55,745,620	53,691,070
Stockholders' deficit:		
Common stock (16,041,464 shares issued and outstanding at March 31, 2023 and December 31, 2022)	1,604	1,604
Additional paid-in capital	190,524,696	190,298,562
Accumulated deficit	(217,686,766)	(210,794,595)
Total stockholders' deficit	(27,160,466)	(20,494,429)
Total liabilities and stockholders' deficit	<u>\$ 28,585,154</u>	<u>\$ 33,196,641</u>

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