

**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): August 3, 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 August 3, 2023, ProSomnus, Inc. (“ProSomnus”) issued a press release announcing its financial results for the three- and six-months ended June 30, 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 |
|-----------------------------|---|
| <u>99.1</u> | <u>Press release issued by ProSomnus, Inc. dated August 3, 2023</u> |
| 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: August 3, 2023

By: /s/ Brian B. Dow

Name: Brian B. Dow

Title: Chief Financial Officer

ProSomnus Reports Record Second Quarter 2023 Top-Line Financial Results

PLEASANTON, Calif., Aug 3, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (“the Company” or “ProSomnus”) (NASDAQ: OSA), a leading CPAP alternative for the treatment of Obstructive Sleep Apnea (“OSA”), today announced financial results for the second quarter ended June 30, 2023.

Recent Business Highlights

- Generated record quarterly revenues of \$6.9 million in the second quarter of 2023, and \$12.7 million in the first half of 2023.
- Delivered a 43% revenue increase from the second quarter of 2022, and a sequential revenue increase of 19% from the first quarter 2023.
- Updated, preliminary data from the Front Line Obstructive Sleep Apnea Treatment study (FLOSAT), a head to head study versus CPAP for moderate and severe OSA, was presented at three sleep industry conferences demonstrating ProSomnus precision devices as efficacious and patient-preferred. Timeline for initial data readout from the Severe Obstructive Sleep Apnea Study (SOS) in the first half of 2024 remains on track.
- Completing development of the next-generation precision OAT featuring embedded remote patient monitoring capabilities, with first commercial use expected in the fourth quarter of 2023.

“ProSomnus delivered record revenues, significant revenue growth and strong organizational execution in the second quarter of 2023,” said Len Liptak, Chief Executive Officer. “The rapidly increasing demand for our precision devices, buttressed by new clinical data supporting the effectiveness of our precision therapy, represents meaningful progress towards achieving our vision of making ProSomnus devices the leading treatment for OSA. Data presented by KOLs at scientific conferences further associated ProSomnus devices with effective, safe, and patient-preferred treatment. I am proud of our revenue growth which significantly exceeded expectations, and which we believe reflects the investments we have made toward our strategic growth plans. During the second quarter our team executed against these key initiatives including the expansion of our direct sales team, the development of our next generation sensor device, and the fielding of our Severe OSA Study and related severe OSA FDA label expansion.”

Financial Results for the Second Quarter of 2023

Revenues for the second quarter ended June 30, 2023 totaled \$6.9 million, reflecting a 43% increase over \$4.9 million reported for the same period in 2022 and a 19% sequential increase compared to \$5.8 million reported for the first quarter of 2023. Year-to-date through June 30, 2023, revenues increase 48% to \$12.7 million from \$8.6 million for the same period during the prior year. Revenue growth and the underlying growth in deliveries of the Company’s products reflects 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.

Gross margins remain strong and consistent at 54% for the second quarter ended and year-to-date through June 30, 2023. Margins during the second quarter improved modestly compared to 53% for the first quarter of 2023 and 52% compared to the same period during 2022 and decreased slightly compared to year-to-date 2022 of 55%. Gross profit and gross margin include the costs of materials, labor and overhead costs to produce the Company’s products, including the new manufacturing facility into which the Company moved during 2023. The facility quadrupled the Company’s previous capacity and increased overhead costs absorbed into product costs. With the increased facility costs the Company has maintained strong margins and expects to leverage this, and other expenses, as volumes increase thereby increasing gross margin.

Operating expenses increased to \$9.5 million for the second quarter ended June 30, 2023, an increase of \$5.5 million compared to the same period during 2022, and \$2.3 million compared to the first quarter of 2023. Year-to-date operating expenses increased to \$16.7 million, an increase of \$8.7 million compared to the same period last year. Increases in Sales and Marketing reflect planned increases in direct sales resources in the United States and in Europe. Increases in R&D reflect investments being made in the later stages of development of the Company's RPMO₂ sensor enabled appliance that is expected to be introduced in late 2023. General and administrative (G&A) expenses reflect public company and post-listing expenses, including increased audit and review fees for routine filings and registration statements, legal fees for filings and routine compliance and governance, increases in compensation costs associated with hiring permanent and contract staff for public company compliance functions, and increased operational expenses associated with the Company's new facility. The Company's G&A in the first half of 2023 was atypically high as the Company was transitioning to being a public company. The Company expects its G&A expense to decrease in the second half of 2023 but for G&A expense to remain higher than 2022 levels.

Other income and expense includes interest expense on the Company's outstanding senior and subordinated debt and accounting valuation adjustments.

Cash on hand totaled \$6.2 million as of June 30, 2023.

Conference Call and Webcast Information

ProSomnus Chief Executive Officer, Len Liptak, and Chief Financial Officer, Brian Dow, will host a conference call at 5:30 am PT / 8:30 am ET to discuss the Company's quarterly financial results and provide updated financial guidance for the remainder of 2023. Interested parties may register for the conference call using the following link [ProSomnus Q2 2023 Conference Call](#). You may access the live webcast of the conference call by using the following link: [ProSomnus Q2 2023 Webcast](#). The link will also be posted in the Investor Relations section of the ProSomnus website at [News & Events](#).

About ProSomnus

ProSomnus (NASDAQ: [OSA](#)) is a leading CPAP alternative 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.

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three-month period ended | | |
|--|--------------------------|-------------------|------------------|
| | June 30, 2023 | March 31, 2023 | June 30, 2022 |
| Revenue | \$ 6,933,910 | \$ 5,808,380 | \$ 4,859,909 |
| Cost of revenue | 3,170,794 | 2,756,631 | 2,321,692 |
| Gross profit | 3,763,116 | 3,051,749 | 2,538,217 |
| Operating expenses | | | |
| Sales and marketing | 3,642,718 | 2,824,048 | 2,013,392 |
| Research and development | 1,376,036 | 1,018,969 | 669,348 |
| General and administrative | 4,480,124 | 3,353,007 | 1,289,154 |
| Total operating expenses | 9,498,878 | 7,196,024 | 3,971,894 |
| Loss from operations | (5,735,762) | (4,144,275) | (1,433,677) |
| Other income (expense) | | | |
| Interest expense | (1,240,159) | (1,171,810) | (1,197,237) |
| Change in fair value of earnout liability | 6,700,000 | 1,500,000 | — |
| Change in fair value of warrant liability | 2,106,398 | (842,559) | — |
| Change in fair value of debt | (802,430) | (1,827,000) | — |
| Other | (123,117) | (406,527) | (192,731) |
| Total other income (expense) | 6,640,692 | (2,747,896) | (1,389,968) |
| Net income (loss) | \$ 904,930 | \$ (6,892,171) | \$ (2,823,645) |
| Net income (loss) per share attributable to common stockholders: | | | |
| Basic | \$ 0.06 | \$ (0.43) | \$ (0.71) |
| Diluted (1) | \$ (0.01) | \$ (0.43) | \$ (0.71) |
| Weighted average shares outstanding: | | | |
| Basic | 16,048,717 | 16,041,464 | 3,958,258 |
| Diluted | 19,132,318 | 16,041,464 | 3,958,258 |

(1) Diluted net loss per share for the three-month period ended June 30, 2023 includes the effect of the following item:
Interest expense and fair value remeasurement of the Senior Convertible Notes

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Six-month period ended | |
|--|-------------------------------|----------------|
| | June 30, | |
| | 2023 | 2022 |
| Revenue | \$ 12,742,290 | \$ 8,603,052 |
| Cost of revenue | 5,927,425 | 3,900,188 |
| Gross profit | 6,814,865 | 4,702,864 |
| Operating expenses | | |
| Sales and marketing | 6,466,766 | 4,130,811 |
| Research and development | 2,395,005 | 1,226,980 |
| General and administrative | 7,833,131 | 2,642,889 |
| Total operating expenses | 16,694,902 | 8,000,680 |
| Loss from operations | (9,880,037) | (3,297,816) |
| Other income (expense) | | |
| Interest expense | (2,411,969) | (2,293,075) |
| Change in fair value of earnout liability | 8,200,000 | — |
| Change in fair value of warrant liability | 1,263,839 | (20,756) |
| Change in fair value of debt | (2,629,430) | — |
| Other | (529,644) | (192,731) |
| Total other income (expense) | 3,892,796 | (2,506,562) |
| Net loss | \$ (5,987,241) | \$ (5,804,378) |
| Net income (loss) per share attributable to common stockholders: | | |
| Basic and diluted | \$ (0.43) | \$ (1.47) |
| Weighted average shares outstanding: | | |
| Basic and diluted | 16,045,110 | 3,950,009 |

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

| | June 30, 2023 | December 31, 2022 |
|---|--------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 6,175,632 | \$ 15,916,141 |
| Accounts receivable, net | 3,560,882 | 2,843,148 |
| Inventory | 1,309,982 | 639,945 |
| Prepaid expenses and other current assets | 1,162,921 | 1,846,870 |
| Total current assets | 12,209,417 | 21,246,104 |
| Property and equipment, net | 3,265,865 | 2,404,402 |
| Right-of-use assets, net | 9,403,098 | 9,283,222 |
| Other assets | 345,653 | 262,913 |
| Total assets | <u>\$ 25,224,033</u> | <u>\$ 33,196,641</u> |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,072,393 | \$ 2,101,572 |
| Accrued expenses | 5,824,193 | 3,706,094 |
| Current lease liabilities | 1,559,576 | 1,282,603 |
| Total current liabilities | 9,456,162 | 7,090,269 |
| Long term lease liabilities, net of current portion | 8,025,303 | 7,792,617 |
| Senior Convertible Notes at fair value | 12,928,404 | 13,651,000 |
| Subordinated Convertible Notes at fair value | 15,225,000 | 10,355,681 |
| Earnout liability | 4,610,000 | 12,810,000 |
| Warrant liability | 727,664 | 1,991,503 |
| Total noncurrent liabilities | 41,516,371 | 46,600,801 |
| Total liabilities | 50,972,533 | 53,691,070 |
| Stockholders' deficit: | | |
| Common stock, \$0.0001 par value, 100,000,000; 16,057,630 and 16,041,464 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively | 1,606 | 1,604 |
| Additional paid-in capital | 191,031,730 | 190,298,562 |
| Accumulated deficit | (216,781,836) | (210,794,595) |
| Total stockholders' deficit | (25,748,500) | (20,494,429) |
| Total liabilities and stockholders' deficit | <u>\$ 25,224,033</u> | <u>\$ 33,196,641</u> |

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, the outcome and timing for ProSomnus’s trials, ProSomnus’s future growth, expenses and margins, 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 press release 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) uncertainty of the projected financial information with respect to ProSomnus; (ii) ProSomnus’s limited operating history and history of losses; (iii) ProSomnus’s ability to maintain and grow its profit margin from sales of ProSomnus oral devices; (iv) ProSomnus’s ability to expand internationally; (v) the roll-out of ProSomnus’s business and the timing of expected business milestones; (vi) ProSomnus’s ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; (vii) expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; (viii) the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; (ix) risk related to compliance debt covenants or successfully renegotiating such covenants; (x) ProSomnus’s ability to obtain additional funding and the risk of potential future significant dilution to stockholders resulting from any such financing or from lender conversions under the convertible debt financing; (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 most recent annual report 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.

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