

**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): December 20, 2022

VENUS CONCEPT INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38238
(Commission File Number)

06-1681204
(IRS Employer Identification Number)

**235 Yorkland Blvd, Suite 900
Toronto, Ontario M2J 4Y8**
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (877) 848-8430

Not Applicable
(Former name or former address, if changed since last report)

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, \$0.0001 par value per share	VERO	The Nasdaq Capital 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 8.01. Other Events.

On December 21, 2022, Venus Concept Inc. (the “Company”) issued a press release relating to its receipt of 510(k) clearance from the U.S. Food and Drug Administration (the “FDA”) to market AI.ME, the Company’s next generation robotic technology, for fractional skin resurfacing. A copy of the press release regarding the above-described FDA clearance is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated December 21, 2022.
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.

VENUS CONCEPT INC.

Date: December 21, 2022

By: /s/Domenic Della Penna

Domenic Della Penna
Chief Financial Officer

**Venus Concept Receives 510(k) Clearance for Use of its AI.ME™ Next
Generation Robotic Technology for Fractional Skin Resurfacing**

TORONTO, December 21, 2022, (GLOBE NEWSWIRE) - Venus Concept Inc. (“Venus Concept” or the “Company”) (NASDAQ: VERO), a global medical aesthetic technology leader, today announced that it has received a 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) to market its AI.ME next generation robotic technology for fractional skin resurfacing.

“We are very pleased to receive the first FDA regulatory clearance for our non-surgical robotic technology platform, AI.ME, and believe it showcases Venus Concept’s ongoing investment in technology, innovation, and clinical research towards robotics applications in the field of medical aesthetics,” said Rajiv De Silva, Chief Executive Officer of Venus Concept. “AI.ME is a first-of-its-kind robotic platform offering physicians minimally-invasive treatments for high-demand procedures requiring fractional skin resurfacing. We see AI.ME as a versatile platform and we will continue to develop the platform to provide innovative solutions in various areas of medical aesthetics, starting with fractional skin resurfacing. The AI.ME technology will be critical to maximizing the synergy between our well-established medical aesthetic business and our pioneering robotics business driven by a robust R&D pipeline developed by our team in San Jose. This 510(k) clearance brings us one step closer to our goal of commercializing AI.ME in the U.S., and we look forward to introducing our first AI.ME systems with Venus Concept’s leading physician partners in 2023.”

The AI.ME robotic system utilizes an advanced visualization system, machine vision, and Artificial Intelligence algorithms to target the dermis in a pre-planned selective, and predictable manner. It uses a smart array of micro-coring hollow punches to precisely core and excise micro-skin fractions at a precise depth to remove up to 10% of skin in the treatment area, leading to collagen deposition and fractional skin resurfacing of the treated area.

“Integrating the advancements of robotics into the area of minimally-invasive aesthetic procedures is very promising,” said Girish (Gilly) Munavalli, MD, MHS, FACMS board-certified dermatologist and advisor to Venus Concept. “This new technology may become a real game-changer in the area of medical aesthetics, offering a new level of consistency, predictability, and visualization which will differentiate it from existing energy-based solutions. We had the privilege to participate in the early clinical studies of AI.ME and it is clear that the advancements that its robotic technology presents to our practice can go far beyond fractional skin resurfacing. I’m encouraged to see some true innovation in the area of minimally-invasive aesthetic treatments and I’m looking forward to seeing the technology evolve to produce consistent transformational results.”

About Venus Concept

Venus Concept is an innovative global medical aesthetic technology leader with a broad product portfolio of minimally invasive and non-invasive medical aesthetic and hair restoration technologies and reach in over 60 countries and 16 direct markets. Venus Concept's product portfolio consists of aesthetic device platforms, including Venus Versa, Venus Legacy, Venus Velocity, Venus Fiore, Venus Viva, Venus Glow, Venus Bliss, Venus BlissMAX, Venus Epileve, Venus Viva MD, and AI.ME. Venus Concept's hair restoration systems include NeoGraft® and the ARTAS iX® Robotic Hair Restoration system. Venus Concept has been backed by leading healthcare industry growth equity investors including EW Healthcare Partners (formerly Essex Woodlands), HealthQuest Capital, Longitude Capital Management, Aperture Venture Partners, and Masters Special Situations.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. In some cases, you can identify these statements by words such as such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements include, but are not limited to, statements about our financial performance; the growth in demand for our systems and other products; and general economic conditions, including the global economic impact of COVID-19, and involve risks and uncertainties that may cause results to differ materially from those set forth in the statements. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which the Company operates and management's beliefs and assumptions and are not guarantees of future performance or developments and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this communication may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described under Part II Item 1A—"Risk Factors" in our Quarterly Reports on Form 10-Q and Part I Item 1A—"Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the date of this communication. Unless required by law, the Company does not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

Investor Relations Contact:

ICR Westwicke on behalf of Venus Concept:

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