

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 31, 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 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 8.01. Other Events.**

On March 31, 2022, Venus Concept Inc. (the “Company”) submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (“FDA”), which is intended to obtain a general clinical indication related to the use of its Aime robotic technology for tissue excision and skin resurfacing. A copy of the press release relating to the above-described FDA submission is attached as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	Press release dated March 31, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: March 31, 2022

By: /s/ Domenic Della Penna

Domenic Della Penna  
Chief Financial Officer

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## Venus Concept Submits FDA 510(k) Related to the Use of its Aime™ Next Generation Robotic Technology for Tissue Excision and Skin Resurfacing

**TORONTO, March 31, 2022 (GLOBE NEWSWIRE)** – Venus Concept Inc. (“Venus Concept” or the “Company”) (NASDAQ: VERO), a global medical aesthetic technology leader, today announced it has submitted a 510(k) premarket notification (“510(k)”) to the U.S. Food and Drug Administration (“FDA”), which is intended to obtain a general clinical indication related to the use of its Aime™ next generation robotic technology for tissue excision and skin resurfacing. Aime is a robotic platform designed to provide micro-coring for medical aesthetic applications.

“We are excited to begin the process of obtaining the first FDA regulatory clearance for our non-surgical robotic technology platform, Aime,” said Domenic Serafino, Chief Executive Officer of Venus Concept. “Aime has the potential to bring true innovation to the medical aesthetics market by changing the way procedures are performed and bringing a new level of consistency and predictability. The submission of this 510(k) brings us one step closer to our goal of commercializing Aime in the U.S., and we look forward to beginning a limited release in the fourth quarter of 2022.”

### **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 18 direct markets. Venus Concept focuses its product sales strategy on a subscription-based business model in North America and in its well-established direct global 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 and Venus Viva MD. Venus Concept’s hair restoration systems include NeoGraft®, an automated hair restoration system that facilitates the harvesting of follicles during a FUE process and the ARTAS® and ARTAS iX® Robotic Hair Restoration systems, which harvest follicular units directly from the scalp and create recipient implant sites using proprietary algorithms. 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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