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): February 22, 2022

ORGANOVO HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-35996

Delaware (State or other jurisdiction of incorporation) **27-1488943** (I.R.S. Employer Identification No.)

11555 Sorrento Valley Road, **Suite 100** San Diego, CA 92121 (Address of principal executive offices, including zip code)

(858) 224-1000 (Registrant's telephone number, including area code)

> 440 Stevens Avenue, Suite 200 Solana Beach, CA 92075

(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 (see General Instruction A.2. below):

□ 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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, \$0.001 par value	ONVO	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company \Box

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 1.01. Entry into a Material Definitive Agreement

Organovo Holdings, Inc. (the "Company") previously disclosed the following actions (collectively, the "Actions"):

- In June 2021, the Company's U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to its bioprinter technology, became the subject of Inter Partes Review ("IPR") proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc. (collectively, "Cellink AB"). The Company filed a preliminary response to Cellink AB's IPR petition in September 2021, and the Patent Trial and Appeal Board denied institution of the proceedings in December 2021.
- Also in June 2021, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (licensed exclusively to Organovo, Inc.) were subject to a declaratory judgment complaint against the Company brought by Cellink AB to obtain a declaration from the United States District Court for the District of Delaware that they do not infringe any claims of the noted patents (the "Declaratory Judgment Complaint").
- Further, on July 28, 2021, the Company filed a complaint for patent infringement against Cellink AB in the United States District Court for the Western District of Texas (the "Patent Complaint"). The Patent Complaint alleged that Cellink AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo, Inc.). The Company sought an injunction against continuing infringement of the foregoing patents by Cellink AB and monetary damages. The Company later amended the complaint to add U.S. Patent No. 8,852,932 in the Patent Complaint. The Patent Complaint was transferred to the District of Delaware in December 2021 to be consolidated with Cellink's Declaratory Judgment Complaint.
- In addition, in September 2021, Cellink AB filed two additional IPR proceedings against the Company's U.S. Patent. Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Foundation for Research and Development), which relate to its bioprinter technology. The Company filed preliminary responses to those proceedings in December 2021 and January 2022.

On February 22, 2022, the Company and BICO Group AB, the parent Company of Cellink AB ("BICO"), entered into a settlement and patent license agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, (i) the parties settled and agreed to file to dismiss each of the Actions, (ii) the Company agreed to grant BICO a worldwide, non-exclusive, non-sub-licensable, non-transferable perpetual, irrevocable, license under the Company's patents that were the subject of the Actions (collectively, the "Licensed Patents") with respect to products based on the Licensed Patents (the "Licensed Products") in all fields of use under any BICO brand, OEM customer's private label or in association, (iii) BICO agreed to make an upfront payment of \$1.5 million to the Company, and (iv) BICO agreed to pay the Company ongoing royalties at rates in the range of low to high single digit percentages of net sales of the Licensed Products. The license contained in the Settlement Agreement continues until the expiration of the last surviving Licensed Patent. The Settlement Agreement also contains customary termination, confidentiality and other provisions.

The foregoing description of the Settlement Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of such agreement, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ending on March 31, 2022.

Item 7.01. Regulation FD Disclosure

On February 23, 2022, the Company issued a press release announcing its entry into the Settlement Agreement. The Company's press release is attached as Exhibit 99.1 hereto and is incorporated by reference in this Item 7.01.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the rules or regulations promulgated thereunder ("Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Exhibits
99.1	Press Release, dated February 23, 2022.
104	Cover Page Interactive Date File, formatted in Inline Extensible Business Reporting Language (iXBRL).

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.

Date: February 28, 2022

ORGANOVO HOLDINGS, INC.

By: /s/ Keith Murphy

Keith Murphy Executive Chairman



Organovo and BICO (CELLINK) Reach Licensing Agreement on Bioprinting Patents

February 23, 2022

San Diego, CA, February 23, 2022—Organovo Holdings, Inc. (Nasdaq: ONVO), and BICO today announced they have reached agreement on a broad license for BICO and its affiliate companies to Organovo's foundational patent portfolio in 3D bioprinting. Founded in 2016, BICO (formerly Cellink) is the leading bio convergence company in the world. Cellink continues to operate as a wholly owned division of BICO.

Organovo exclusively licensed early bioprinting work by Gabor Forgacs, its scientific founder, and Thomas Boland of Clemson, both bioprinting pioneers. After its founding, the company did early innovation in the 3D bioprinter space and obtained a further broad set of patents that provide foundational claims in the bioprinting space. In order to broaden the impact of the technology and serve the needs of a broad array of researchers and other users of bioprinting, the company seeks to make these patents available for license to first rate bioprinter developers.

Organovo Executive Chairman Keith Murphy commented, "Organovo celebrates the success of CELLINK's bioprinting product lines in opening up the horizons of 3D bioprinting to customers. We are proud to be a part of enabling CELLINK and BICO to grow these products and we look forward with excitement to their next generation of bioprinters."

Organovo and BICO were engaged in several legal disputes regarding the patents. Under the new agreement, all civil actions regarding potential infringement and IPRs concerning validity of Organovo's patents are dismissed and/or terminated. Both BICO and Organovo have released each other from all previous claims, demands liabilities and costs in favor of the beneficial and sustainable solution created through this patent license agreement.

About Organovo

Organovo is an early-stage biotechnology company that is developing and utilizing highly customized 3D human tissues as dynamic models of healthy and diseased human biology for drug development. The company's proprietary technology is being used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Organovo's advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs for selected therapeutic areas.

Forward Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements include, among others, those related to the potential benefits to Organovo of the licensing agreement between Organovo and BICO. The forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. These risks and uncertainties and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on June 15, 2021, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on February 14, 2022.

You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

Investor Contact

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