
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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 4, 2021**

Todos Medical Ltd.

(Exact name of registrant as specified in its charter)

Israel
(State or other jurisdiction
of incorporation or organization)

000-56026
(Commission
File Number)

n/a
(IRS Employer
Identification No.)

1 Hamada Street
Rehovot, Israel 224427
Tel: (011) (972) 8-633-3964
(Address of principal executive offices)

Registrant's telephone number, including area code: **+972-8-633-3964**

(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 communication 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: None

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 May 4, 2021, Todos Medical Ltd. (the "Company") announced that the US Food & Drug Administration granted the Company a new Certificate of Free Sale for a second dosing regimen for Tollovid™ as a dietary supplement. Under the new Certificate of Free Sale, the Company is authorized to market Tollovid with a dosing regimen of 60 pills over a five-day period, equivalent to 12 pills per day.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release dated May 4, 2021.](#)

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SIGNATURE

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.

Dated: May 4, 2021

TODOS MEDICAL LTD.

By: /s/ Gerald Commissiong
Gerald Commissiong

Todos Medical Receives FDA Certificate of Free Sale for New 5 Day Tollovid™ Dosing Regimen

- *Company sees this new dosing regimen of 60 pills over 5 days as optimal for Tollovid, the Company's 3CL protease inhibitor botanical dietary supplement that helps to support and maintain healthy immune function*

NEW YORK, NY, and REHOVAT, ISRAEL – May 4, 2021 - Todos Medical, Ltd. (OTCQB: TOMDF), a comprehensive medical diagnostics and related solutions company, today announced that the US Food & Drug Administration granted the Company a new Certificate of Free Sale for a second dosing regimen for Tollovid™ as a dietary supplement. Under the new Certificate of Free Sale, the Company is authorized to market Tollovid with a dosing regimen of 60 pills over a five-day period, equivalent to 12 pills per day. Tollovid, a potent 3CL protease inhibitor botanical product, is a dietary supplement that helps to support and maintain healthy immune function. The 3CL protease is an important part of certain coronavirus' reproductive mechanism and inhibiting this protease may help to support and maintain healthy immune function in the face of circulating coronaviruses. The Company sees this dosing regimen for Tollovid as optimal for supporting healthy immune function.

"We were very pleased with the speed with which this dosing regimen for Tollovid was granted a new Certificate of Free by the US FDA," said Gerald E. Commissiong, President & CEO of Todos Medical. "After a successful initial launch at The Alchemist's Kitchen in New York City, where we gained significant feedback from customers on what worked best for them with Tollovid, we developed an upgraded dosing regimen based on the first-hand experience of customers that had a successful experience with the product. With that critical information and this new Certificate of Free Sale in hand, we are now preparing to launch Todos Medical's branded Tollovid product into the US market via a soon to be launched website www.MyTollovid.com in a direct-to-consumer model with overnight shipping. We also intend to explore opportunities to distribute Tollovid in other areas of the world that are eagerly seeking new products that can potentially inhibit 3CL protease, and are in active discussions with distributors to bring this product forward in those markets.

The Company intends to utilize a portion of the proceeds from a recently completed \$3.3 million fixed price crossover investment with Yozma Group, a venture capital firm from South Korea to help with the Tollovid launch. With Yozma's recent investment, Todos has raised \$9.7 million in this crossover round since January 2021. In addition to the Tollovid launch, the Company is utilizing the proceeds from these investments to retire certain outstanding debts, further advance the ongoing Phase 2 clinical trial of the Company's oral 3CL protease targeting drug candidate Tollovir™ for hospitalized COVID-19 patients, the completion of initial clinical studies for the Company's 3CL protease targeting COVID-19 diagnostic assay Tollostest™ and general corporate purposes.

For information related to Todos Medical's COVID-19 testing capabilities, please visit www.todoscovid19.com.

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For COVID-19 testing inquiries, please email sales@todosmedical.com.

About Todos Medical Ltd.

Founded in Rehovot, Israel with offices in New York City, Todos Medical Ltd. (OTCQB: TOMDF), engineers life-saving diagnostic solutions for the early detection of a variety of cancers. The Company's state-of-the-art and patented Todos Biochemical Infrared Analyses (TBIA) is a proprietary cancer-screening technology using peripheral blood analysis that deploys deep examination into cancer's influence on the immune system, looking for biochemical changes in blood mononuclear cells and plasma. Todos' two internally-developed cancer-screening tests, TMB-1 and TMB-2, have received a CE mark in Europe. Todos recently acquired U.S.-based medical diagnostics company Provista Diagnostics, Inc. to gain rights to its Alpharetta, Georgia-based CLIA/CAP certified lab currently performing PCR COVID testing and Provista's proprietary commercial-stage Videssa® breast cancer blood test.

Todos is also developing blood tests for the early detection of neurodegenerative disorders, such as Alzheimer's disease. The Lymphocyte Proliferation Test (LymPro Test™) is a diagnostic blood test that determines the ability of peripheral blood lymphocytes (PBLs) and monocytes to withstand an exogenous mitogenic stimulation that induces them to enter the cell cycle. It is believed that certain diseases, most notably Alzheimer's disease, are the result of compromised cellular machinery that leads to aberrant cell cycle re-entry by neurons, which then leads to apoptosis. LymPro is unique in the use of peripheral blood lymphocytes as a surrogate for neuronal cell function, suggesting a common relationship between PBLs and neurons in the brain.

Todos has entered into distribution agreements with companies to distribute certain novel coronavirus (COVID-19) test kits. The agreements cover multiple international suppliers of PCR testing kits and related materials and supplies, as well as antibody testing kits from multiple manufacturers after completing validation of said testing kits and supplies in its partner CLIA/CAP certified laboratory in the United States. Todos has formed a strategic partnership with Integrated Health LLC to deploy mobile COVID-19 testing in the United States. Additionally, Todos has entered into a joint venture with NLC Pharma to pursue the development of diagnostic tests targeting the 3CL protease, as well as 3CL protease inhibitors that target the reproductive mechanism of coronaviruses.

For more information, please visit <https://www.todosmedical.com/>.

Forward-looking Statements

Certain statements contained in this press release may constitute forward-looking statements. For example, forward-looking statements are used when discussing our expected clinical development programs and clinical trials. These forward-looking statements are based only on current expectations of management, and are subject to significant risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for product candidates; competition from other biotechnology companies; and our ability to obtain additional funding required to conduct our research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching our clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; and laboratory results that do not translate to equally good results in real settings, all of which could cause the actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Todos Medical does not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Todos Medical, please refer to its reports filed from time to time with the U.S. Securities and Exchange Commission.

Todos Corporate and Investor Contact:

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