# 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): **November 15, 2021**

# Todos Medical Ltd.
(Exact name of registrant as specified in its charter)

| **Israel** | **000-56026** | **n/a** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | IRS Employer Identification No.) |

**121 Derech Menachem Begin, 30th Floor**
**Tel Aviv, 6701203 Israel**
(Address of principal executive offices)

Registrant's telephone number, including area code: **972 (52) 642-0126**

(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:

| **Title of each class:** | **Trading Symbol(s)** | **Name of each exchange on which registered:** |
|---|---|---|
| n/a | n/a | n/a |

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 November 15, 2021, Todos Medical Ltd. issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits.

99.1 Press Release dated November 15, 2021
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)



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: November 16, 2021

TODOS MEDICAL LTD.

By: */s/ Gerald Commissiong*
Gerald Commissiong
Chief Executive Officer

**Exhibit 99.1**

**Todos Medical Reports Third Quarter 2021 Business and Financial Results**

**New York, NY, and Tel Aviv, ISRAEL – November 15, 2021 - Todos Medical, Ltd. ("Todos Medical") (OTCQB: TOMDF)** , a comprehensive medical diagnostics and related solutions company, announced financial results today for the third quarter ended September 30, 2021.

**Corporate Highlights**

***Integration of COVID-19 PCR automation at recently acquired CLIA/CAP lab Provista drives revenues***

Provista is our CLIA/CAP diagnostic testing laboratory in Alpharetta, GA currently performing PCR testing for (1) COVID-19, (2) COVID variant screening and (3) respiratory pathogen panel (RPP) testing, as well as (4) cPass neutralizing antibody blood test. The integration of the automation prepared the Company to handle increased demand heading into the fourth quarter of 2021. When at full capacity the lab has automation in place to perform up to (1) 20,000+ PCR tests/day, (2) 5,000 variant tests/day, (3) 2,500+ RPP tests/day and (4) 1,500+ cPass neutralizing antibody tests/day.

***Positive data announced from 2020 observational Phase 1/2 clinical trial of 3CL Oral Antiviral 3CL Protease Inhibitor NLC-V-01 (Tollovir®) in Hospitalized COVID-19 Patients***

The exploratory 2020 observational study of 32 patients was comprised of 11 treated patients compared with 21 randomly selected untreated patients in the hospitalized setting who had similar baseline characteristics during the time the 11 patients were voluntarily recruited into the study. All clinical results were collected by the Company's joint venture partner NLC Pharma in Israel. Results showed zero deaths in the Tollovir-treated group versus 5 deaths in the observed group. The mean age was slightly higher in the Tollovir group. The biomarker C-Reactive Protein (CRP) was measured upon hospitalization and tallied the number of patients that were able to experience a 50% reduction in this inflammatory biomarker within 48 – 72 hours. In the Tollovir group, 50% of the patients experienced a reduction of 50% or more in CRP versus only 10% in the observed group. Tollovir appeared to be well tolerated and showed only minor incidences of diarrhea which is consistent with the disease.

| | Tollovir® | Control |
|---|---|---|
| **Number of patients treated** | 11 | 21 |
| **Age (mean; range)** | 75 (45-87) | 73 (60-90) |
| **Hospitalization Days (mean; range)** | 13.3 (6-19) | 17.4 (4-41) |
| **Died in hospital** | 0 | 5 |
| **Deteriorated to respirator and recovered** | 0 | 3 |
| **CRP reduction of 50% and more within 48-72 hours** | 5 | 2 |



***Continued enrollment in ongoing Phase 2 randomized, double-blinded, placebo-controlled clinical trial of Tollovir in hospitalized COVID-19 patients in Israel***

The new randomized, double-blinded, placebo-controlled trial is being conducted at Shaare Zedek Medical Center in Jerusalem, Israel to evaluate the safety and efficacy of Tollovir for the treatment of COVID-19 in hospitalized patients who had enrolled 22 patients as of 9/30/21. Tollovir is a patent-pending therapeutic agent being developed through a joint venture between Todos Medical and NLC Pharma. 3CL protease inhibitors are targeted as desirable candidates for the development of antiviral therapies against SARS-CoV-2 (the virus that causes COVID-19), with Pfizer developing the 3CL protease inhibitor PAXLOVID™ in the outpatient setting. Todos expects to provide interim data results in the fourth quarter of 2021.

The Company has retained a CRO in India to expand the clinical development of Tollovir and intends to make final decisions on pivotal clinical development plans for (1) hospitalized (severe and critical) patients, (2) moderate patients in the outpatient setting, (3) long haul COVID and (4) pediatric COVID following completion of the interim analysis.

***Amazon and Alibaba grant authorization to sell Tollovid® and Tollovid Daily™ on their platforms***

Tollovid, a potent 3CL protease inhibitor, is a dietary supplement that helps to support and maintain healthy immune function over a 12 pill daily, 5-day dosing regimen when ultimate immune support is needed. Tollovid Daily, a lower dose 3CL protease inhibitor, is a dietary supplement that helps to support and main healthy immune function over a 2 pill daily, 30 days per month dosing regimen to provide ongoing immune support for the person on the go. Amazon and Alibaba both granted authorization to sell Tollovid and Tollovid Daily on their platforms in the third quarter of 2021, in addition to the products being available at www.MyTollovid.com.

*Disclaimer: Tollovid and Tollovid Daily are dietary supplements that have received certificates of free sale (CFS) authorizing their sale in the United States. Tollovid and Tollovid Daily have not been approved by the U.S. Food & Drug Administration to diagnose, treat, prevent or cure any disease.*

***Videssa® Breast Bancer Blood Test Advancements***

The Company has begun preparations for the analytical and clinical performance studies required to relaunch Videssa in the United States. The Company expects analytical performance studies to begin in the first quarter of 2022 and be completed by the third quarter of 2022, and then to complete the clinical performance studies with clinical samples gathered beginning in the first quarter of 2022. The Company has been in discussion with various groups conducting breast cancer clinical research and expects to complete its due diligence and contracting in the fourth quarter of 2021. The Company intends to launch Videssa in the United States via its Provista CLIA/CAP lab.

***Appointment of Ilanit Halperin, CFA as Corporate Controller***

The Company appointed Ilanit Halperin, CPA as its Corporate Controller. Ms. Halperin, the principal of Halperin Ilanit, CPA, has over 25 years of financial reporting, accounting and auditing experience. Prior to forming Halperin Ilanit CPA in 2018, Ms. Halperin was a partner of Fahn Kanne Grant Thornton Israel, the sixth largest CPA firm in Israel and the Israeli member firm of Grant Thornton International Ltd. From 2011 until 2017, she was head of the firm's High-Tech and Life Sciences Department. During her tenure at Fahn Kanne Grant Thornton Israel, Ms. Ilanit was the audit engagement partner of several companies listed in the United States.



**Financial Highlights for Q2 2021**

**Revenues:** Total revenue in the third quarter of 2021 was $1.01 million vs. revenues of $1.28 million in 2021. The decrease in revenues was primarily driven by a shift away from equipment sales to reagent sales in its Corona Diagnostics laboratory products distribution business. The Company expects to focus on driving revenue growth in COVID 19 related diagnostics as well as other testing services through its Provista Diagnostics CLIA/CAP lab business unit. The Company anticipates a significant revenue increase in revenue at Provista beginning in the fourth quarter of 2021 and progressively throughout 2022.

**Loss from Operations:** The Company recorded an operating loss of $(2,497,000) in the third quarter of 2021 compared to an operating loss of $(10,246,000) in the third quarter of 2020. The 75% decrease in net loss was largely a result of $8.2 million in IPR&D expense recorded in 2020 related to the Company's acquisition of certain diagnostic assets, coupled with reductions in professional fees related to R&D, laboratory and materials expense, and sales and marketing expenses, partially offset by an increase in general and administrative expenses.

**Net Income:** The Company recorded net loss of ($10,379,000) in the third quarter of 2021 compared to a net loss of ($18,035,000) in the third quarter of 2020, largely due to the reduction in expenses previously discussed. Net loss per share in the third quarter of 2021 was ($0.02) on 586.8 million weighted average shares outstanding compared to the third quarter of 2020 where the Company incurred a net loss of $(0.07) per share on 257.3 million weighted average shares outstanding.

**Select Balance Sheet Items:** The Company had cash of $166,000, trade receivables of $2,072,000 and inventory of $1,904,000 as of September 30, 2021, compared to cash of $935,000, trade receivables of $378,000, and inventory of $601,000 as of December 31, 2020. Total assets as of September 30, 2021, were $17,161,000 compared to $6,009,000 as of December 31, 2020. Shareholder deficit decreased to $(10,499,000) as of September 30, 2021, compared to $(11,001,000) as of December 31, 2020.

"The third quarter was focused on preparing to transition the Company's diagnostics revenues towards higher margin COVID-related testing at Provista Diagnostics in preparation for an expected surge in COVID cases in the fourth quarter of 2021. We expect a surge similar to the one seen in the fourth quarter of 2020 as temperatures cool in the United States and people head indoors to congregate over the holiday seasons in November and December," said Daniel Hirsch, CFO of Todos Medical. "With the automation at Provista complete, we expect to capture a greater percentage of our future business from our own testing lab rather than through distribution. We expect this to result in increases in revenue and gross margins overall and on a per test basis. We are pleased with the progress we have made to have Tollovid and Tollovid Daily approved for sale on the Amazon and Alibaba platforms. We expect that availability through these marquee distribution outlets will help build sales momentum heading into the winter months as people seek to add protease inhibition as a part of supporting a healthy immune system. In addition, the pending interim data readout in the ongoing Tollovir clinical trial in hospitalized COVID-19 patients has the potential to substantially increase the value of this important asset heading into the end of the year as we continue to execute on our strategy for the planned uplisting of Todos Medical's ordinary shares to a national stock exchange in the near future."



**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. In 20201, Todos completed the acquisition of 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. 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 is focused on the commercialization of Videssa and will bring the TBIA tests to market thereafter.

Todos has entered into a joint venture with NLC Pharma targeting diagnostic and testing solutions to address the COVID-19 pandemic. The Joint-Venture is pursuing the development of diagnostic tests targeting the 3CL protease, as well as 3CL protease inhibitors that target a fundamental reproductive mechanism of coronaviruses. The Company's proprietary therapeutic candidate Tollovir™ is currently in a Phase 2 clinical trial to treat hospitalized COVID-19 patients in Israel, and is preparing to initiate Phase 2/3 clinical trials for both hospitalized and non-hospitalized patients in Israel.

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 is also distributing certain (COVID-19) testing materials and supplies to CLIA-certified labs in the United States. The products cover multiple suppliers of PCR testing kits, extraction kits, automation materials and supplies, as well as COVID-19 antibody and antigen testing kits.

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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**CONDENSED CONSOLIDATED BALANCE SHEETS**
(U.S. dollars in thousands except share and per share amounts)

| | As of September 30, 2021 | As of December 31, 2020 |
|---|---|---|
| | Unaudited | |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 166 | $ 935 |
| Trade receivables | 2,072 | 378 |
| Inventories | 1,904 | 536 |
| Other current assets | 129 | 601 |
| Total current assets | 4,271 | 2,450 |
| | | |
| **Non-current assets:** | | |
| Investment in affiliated companies accounted for under equity method, net | 40 | 745 |
| Investment in other company | 455 | 224 |
| Property and equipment, net | 2,591 | 1,999 |
| Right of use asset arising from operating lease | 182 | - |
| Prepaid expenses | 361 | 591 |
| Goodwill | 7,761 | - |
| Intangible assets | 1,500 | - |
| Total non-current assets | 12,890 | 3,559 |
| | | |
| **Total assets** | $ 17,161 | $ 6,009 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' DEFICIT** | | |
| **Current liabilities:** | | |
| Receivables financing facility, net | $ - | $ 1,306 |
| Loans, net | 3,205 | 1,672 |
| Accounts payable | 1,169 | 1,640 |
| Deferred revenues | 13 | 844 |
| Other current liabilities | 3,450 | 2,316 |
| Liability for minimum royalties | 355 | 291 |
| Total current liabilities | 8,192 | 8,069 |
| | | |
| **Non-current liabilities:** | | |
| Convertible bridge loans, net | 17,017 | 5,965 |
| Derivative warrants liability, net | 2 | 301 |
| Fair value of bifurcated convertible feature of convertible bridge loans | 1,873 | 2,500 |
| Lease liability arising from operating lease | 86 | |
| Deferred taxes | 315 | - |
| Liability for minimum royalties | 175 | 185 |
| Total non-current liabilities | 19,468 | 8,951 |
| | | |
| **Shareholders' deficit:** | | |
| Ordinary Shares of NIS 0.01 par value each: Authorized: 1,000,000,000 shares at September 30, 2021 and December 31, 2020; Issued and outstanding: 874,813,050 shares and 376,335,802 shares at September 30, 2021 and December 31, 2020, respectively | 2,593 | 1,059 |
| | | |
| Additional paid-in capital | 58,735 | 35,211 |
| Accumulated deficit | (71,827) | (47,281) |
| Total shareholders' deficit | (10,499) | (11,011) |
| | | |
| **Total liabilities and shareholders' deficit** | $ 17,161 | $ 6,009 |



**CONDENSED STATEMENTS OF OPERATIONS**
(U.S. dollars in thousands except share and per share amounts)

| | Nine months period ended September 30, | | Three months period ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | Unaudited | | Unaudited | |
| Revenues | $ 7,773 | $ 1,316 | $ 1,010 | $ 1,284 |
| Cost of revenues | (5,191) | (894) | (1,043) | (883) |
| Gross profit (loss) | 2,582 | 422 | (33) | 401 |
| | | | | |
| Research and development expenses | (835) | (9,655) | (192) | (9,086) |
| Sales and marketing expenses | (2,387) | (2,187) | (429) | (757) |
| General and administrative expenses | (5,048) | (1,729) | (1,843) | (804) |
| | | | | |
| **Operating loss** | (5,688) | (13,149) | (2,497) | (10,246) |
| | | | | |
| Financing expenses, net | (17,360) | (11,375) | (6,875) | (7,055) |
| Share in losses of affiliated companies accounted for under equity method, net | (1,499) | (734) | (1,007) | (734) |

| | | | | |
|---|---|---|---|---|
| **Net loss** | $ (24,547) | $ (25,258) | $ (10,379) | $ (18,035) |
| **Basic and diluted net loss per share** | $ (0.04) | $ (0.12) | $ (0.02) | $ (0.07) |
| **Weighted average number of ordinary shares outstanding attributable to ordinary shareholders used in computation of basic and diluted net loss per share** | 637,916,356 | 210,806,186 | 586,789,080 | 257,276,039 |