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Todos Medical Reports Fourth-Quarter and Full-Year 2021 Financial Results and Corporate Updates

New York, NY, and Tel Aviv, ISRAEL, April 01, 2022 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- **Todos Medical, Ltd. (OTCQB: TOMDF)**, a comprehensive medical diagnostics and related solutions company, today reported financial results for the fourth quarter and full-year ended December 31, 2021 and provided corporate updates.

"2021 was a strong year for Todos Medical and we believe sets the stage for an even stronger year of growth in 2022. We have invested heavily in our newly-acquired Provista Diagnostics lab capabilities and leadership in order to be properly positioned to capture cyclical COVID testing revenue in preparation for the launch of our Videssa breast cancer blood test in early 2023," said Gerald E. Commissiong, President & CEO of Todos Medical. "We also recently completed the acquisition of the 3CL protease assets of NLC Pharma that positions us as the majority owner of 3CL Pharma Ltd. This dramatically improves our capability to bring to market multiple generations of treatments and diagnostics for coronaviruses, beginning with COVID-19."

Mr. Commissiong continued, "We had positive results from the Tollovir Phase 2a clinical trial in hospitalized COVID-19 patients, showing superiority to the current standard of care of Remdesivir + dexamethasone, which positions 3CL Pharma to initiate Phase 2b/3 studies in the hospitalized setting. This data allows us to plot our international regulatory authorizations strategy for Tollovir, with an initial focus on an EUA submission in Greece. Tollovid Daily sales were paused to minimize confusion in the market while we gather market research on outcomes from Tollovid Maximum Strength's use in hopes of pursuing the OTC drug regulatory strategy for acute COVID, Long COVID and pediatric COVID. We are seeing marked increase in interest in 3CL protease inhibitors' use in Long COVID given recent case reports from physicians about Pfizer's Paxlovid potential benefit in Long COVID, and the appointment of our first official Tollovid brand ambassador Billy Blanks who supports the use of Tollovid as a the only 3CL protease inhibitor that can be purchased directly by consumers today. Together, our testing and treatment strategy for COVID-19 fits squarely in the 'Test to Treat' paradigm President Biden outlined was the future strategy to address the COVID-19 pandemic, and we are now well positioned to drive revenue growth in COVID testing and treatments, as well as in dietary supplements."

Corporate Highlights:

Completed Acquisition of Key Assets and Intellectual Property from NLC Pharma

Todos Medical recently acquired all the key assets and intellectual property from NLC

Pharma. The completion of the acquisition forms a new subsidiary, 3CL Pharma, focused on the development and commercialization of 3CL protease-related products including Tollovir™, Tollovid®, Tollovid Daily™ and TolloTest™ for COVID-19. It positions Todos Medical as the leader of oral antivirals for hospitalized COVID-19 patients to speed time to discharge. Key data from the Tollovir Phase 2 clinical trial showed a reduction of 7.2 days of hospitalization, with 100% of patients meeting the criteria for clinical improvement as measured by NEWS2 compared with 66% in the control group. The Company's development plans include Tollovir EUA submissions for Worldwide use and preparations for Phase 2b/3 pivotal, and Tollovid initial real-world study to investigate conversion from dietary supplement to over-the-counter drug for long COVID and pediatrics uses.

Announced Positive Primary and Secondary Endpoints Met in NLC-V-01 Phase 2 Clinical Trial of Oral Antiviral 3CL Protease Inhibitor Tollovir™ in the Treatment of Hospitalized COVID-19 Patients Tollovir™ 2022 Double-Blinded Clinical Trial Results

The Phase 2 clinical trial of Tollovir marked a major milestone for Todos Medical and provides the next steps for the Company's long-term growth plans. Importantly, this has the potential to modify current standards of care. Todos has maintained a strong relationship with NLC and has been highly collaborative and productive providing key discoveries that have the potential to alter the course of the COVID-19 pandemic. Current standard of care (SOC) includes remdesivir and dexamethasone therapy. Phase 2 clinical trial of Tollovir included current standard of care in addition to using Tollovir.

Phase 2 Clinical Trial Results: (Tollovir + SOC vs. SOC alone)

- Mean Reduction of 7.2 days in the hospital
- 100% of Tollovir patients achieved clinical improvement per NEWS2 rating scale versus 66% in placebo arm
- 0% Tollovir death rate while on therapy versus 22% death rate while on therapy in placebo arm
- 73% need for supplement O₂ on Tollovir versus 89% need for O₂ on placebo
 - 3.8 days on supplement O₂ on Tollovir versus 5.8 days on supplement O₂ on placebo
- Improvement across all biomarkers on Tollovir vs. Placebo

PCR Testing Lab revenue expected to Continue Growth: \$5M in 2020 and \$12M in 2021

Over the course of the second half of 2021, the Company invested heavily to automate CLIA/CAP laboratory Provista Diagnostics in order to be able to perform high quantity PCR testing, primarily for COVID-19, in addition to continuing to distribute PCR testing reagents and supplies to client COVID labs. The fourth quarter of 2021 saw strong growth in the Provista COVID testing business and the Company expects revenues to continue to grow significantly in 2022 as the Company begins to expand its test menu to offer other diagnostics tests for respiratory infections, sexually transmitted infections, uterine tract infections, gastrointestinal, cancer genetics and pharmacogenomics, with its respiratory panel already validated and now being used by physicians. This test menu expansion will allow the Company to service women's health clinics, skilled nursing homes, cancer diagnostic and treatment centers, OB-GYN physicians and primary care physicians the Company expects to be the primary prescribers of the Videssa breast cancer blood test.

Proprietary testing: Videssa breast cancer test and LymPro Alzheimer's test

Todos Medical has collected more than 1,000 clinical samples in several clinical trials for breast and other cancers. The latest clinical trial for Todos Medical's breast cancer test included 59 patients and achieved 93% sensitivity and 87% specificity, as compared to routine mammography screening. The Company intends to launch a clinical study in 2022 to meet the criteria to bring this important test into the market and gain initial reimbursement that will allow the Company to drive sales in 2023.

In addition, the Company is conducting the second stage of an ongoing clinical trial for our LymPro Alzheimer's blood test at the University of Leipzig in Germany with a readout expected in the first half of 2022. If successful, LymPro, a dynamic functional assay that measures immune response in the blood that mimics ongoing pathology in the brain, will become an important tool to qualify patients who are most likely to benefit from amyloid treatment. LymPro measures the fundamental underlying biology of Alzheimer's disease and the Company believes it can be identified at the pre-symptomatic phase given that key LymPro markers appear to be stage-independent even at the mild cognitive impairment stage.

Corporate Plans for Uplist to a National Stock Exchange

The Company continues to position itself for a national stock exchange in 2022. The Company expects to file initial public offering documents with the Securities and Exchange Commission needed to complete the transaction in the 2nd quarter of 2022.

Financial Highlights for the Fourth Quarter:

Total revenue in the fourth quarter of 2021 was \$4.46 million versus revenues of \$3.99 million in 2020. The increase in revenues was primarily driven by a higher rate of COVID testing and Tollovid revenues. 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. Revenue increased in the fourth quarter at Provista and expected to progressively grow throughout 2022. Revenue per test was up to \$250 with average of approximately \$80 per test. Total revenue for the full year 2021 was \$12.28 million versus revenues of \$5.21 million in 2020 which represents a 136% increase. During the first 9 months of 2021 revenue from Covid Testing and Tollovid increased 492% to \$7.7 million for versus \$1.3 million for 2020. The Company is focused on stable revenue growth in our testing supplies business (Corona Diagnostics) and exponential growth in of lab services testing business (Provista Labs).

Loss from Operations:

The Company recorded an operating loss of \$3.59 million in the fourth quarter of 2021 compared to an operating loss of \$1.11 million in the fourth quarter of 2020. The increase in net loss was largely a result of unpaid accounts receivable that is being pursued legally. The Company recorded an operating loss of \$9.0 million for the full year 2021 compared to an operating loss of \$14.3 million for the full year 2020.

Net Income:

The Company recorded a net loss of \$18.77 million in the fourth quarter of 2021 compared to a net loss of \$4.52 million in the fourth quarter of 2020, largely due to a reduction in expenses. Net loss per share in the fourth quarter of 2021 was \$0.12 on 586.8 million weighted average shares outstanding compared to the fourth quarter of 2020 where the

Company incurred a net loss of \$0.11 per share on 259.2 million weighted average shares outstanding. The Company recorded a net loss of \$41.0 million for the full year 2021 compared to a net loss of \$29.8 million for the full year 2020.

Select Balance Sheet Items:

The Company had cash of \$189,000, trade receivables of \$2.8 million and inventory of \$1.8 million as of December 31, 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 December 31, 2021, were \$17.4 million compared to \$6.0 million as of December 31, 2020. Shareholder deficit was \$21.9 million as of December 31, 2021, compared to \$11.0 million as of December 31, 2020.

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 using peripheral blood lymphocytes as a surrogate for neuronal cell function, suggesting a common relationship between PBLs & 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 entered into a joint venture with NLC Pharma, Ltd. called 3CL Pharma, Ltd. to pursue the development of oral antiviral therapeutics, dietary supplements and diagnostic tests targeting the 3CL protease. 3CL protease inhibitors target a fundamental 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.

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CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands except share and per share amounts)

	As of December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$189.00	\$935.00
Trade receivables	\$2,520.00	\$378.00
Inventories	\$1,603.00	\$536.00
Other current assets	\$404.00	\$601.00
Total current assets	\$4,716.00	\$2,450.00
Non-current assets:		
Investment in affiliated companies, net	\$40.00	\$745.00
Investment in other company	\$455.00	\$224.00
Property and equipment, net	\$2,045.00	\$1,999.00
Right of use asset arising from operating lease	\$143.00	-
Prepaid expenses	-	\$591.00
Goodwill	\$6,216.00	-
Intangible assets	\$1,500.00	-
Total non-current assets	\$10,399.00	\$3,559.00
Total assets	\$15,115.00	\$6,009.00
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Receivables financing facility, net	\$ -	\$1,306.00
Loans, net	\$2,023.00	\$1,672.00
Accounts payable	\$2,276.00	\$1,640.00
Deferred revenues	-	\$844.00
Other current liabilities	\$4,284.00	\$2,316.00
Liability for minimum royalties	\$377.00	\$291.00
Total current liabilities	\$8,960.00	\$8,069.00
Non-current liabilities:		
Convertible bridge loans, net	\$25,406.00	\$5,965.00
Derivative warrants liability, net	-	\$301.00
Fair value of bifurcated convertible feature of convertible bridge loans	\$4,182.00	\$2,500.00
Operating lease liability	\$141.00	-
Deferred taxes	\$315.00	-
Liability for minimum royalties	\$183.00	\$185.00
Other non-current liabilities	\$140.00	-
Total non-current liabilities	\$30,367.00	\$8,951.00
Commitments and contingent liabilities		
Shareholders' deficit:		
Ordinary Shares of NIS 0.01 par value each:		
Authorized: 5,000,000,000 and 1,000,000,000 shares at December 31, 2021 and 2020, respectively; Issued and outstanding: 975,644,432 shares and 376,335,802 shares at December 31, 2021 and 2020, respectively.	\$2,913.00	\$1,059.00
Redeemable Preferred shares: Authorized: 50,000 at December 31, 2021, non-issued.	-	-
Preferred B Shares: Authorized: 5,000 at December 31, 2021, non-issued.	-	-
Additional paid-in capital	\$63,470.00	\$35,211.00
Accumulated deficit	\$(90,595.00)	\$(47,281.00)
Total shareholders' deficit	\$(24,212.00)	\$(11,011.00)
Total liabilities and shareholders' deficit	\$15,115.00	\$6,009.00

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

	Year ended December 31,	
	2021	2020
Revenues	\$12,230.00	\$5,207.00
Cost of revenues	\$(7,847.00)	\$(3,818.00)
Gross profit	\$4,383.00	\$1,389.00
Research and development expenses	\$(824.00)	\$(9,863.00)
Sales and marketing expenses	\$(3,481.00)	\$(3,058.00)
General and administrative expenses	\$(9,364.00)	\$(2,729.00)
Operating loss	\$(9,286.00)	\$(14,261.00)
Financing income (expenses), net	(30,340)	(14,312)
Impairment losses	\$(2,030.00)	-
Share in losses of affiliated companies	\$(1,658.00)	\$(1,200.00)
Net loss for the year	\$(43,314.00)	\$(29,773.00)
Basic and diluted net loss per share	\$(0.06)	\$(0.11)



Source: Todos Medical Ltd.