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Todos Medical Reports Second Quarter 2021 Financial Results

Company recorded positive earnings of \$0.01 per share as financial condition improved

New York, NY, and Tel Aviv, ISRAEL, Sept. 24, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- **Todos Medical, Ltd. ("Todos Medical") (OTCQB: TOMDF)** a comprehensive medical diagnostics and related solutions company, announced financial results today for the second quarter of 2021 ended June 30, 2021.

Corporate Highlights

Acquired Provista Diagnostics and Its Proprietary Videssa Breast Cancer Blood Test

Provista is a medical diagnostics company based in Alpharetta, Georgia that owns the intellectual property rights to the proprietary breast cancer blood test, Videssa®, and has a CLIA/CAP diagnostic testing laboratory currently performing COVID-19 PCR testing, primarily for the medical and entertainment industries. Todos Medical has begun ramping up Provista's automated testing capacity as well as expanding its testing capabilities to include COVID variant testing and neutralizing antibody testing. When at full capacity the lab has automation in place to do up to 20,000 PCR tests, over 1,500 cPass neutralizing antibody tests, and 5,000 variant tests on a daily basis.

Videssa was developed to provide physicians with actionable information regarding breast cancer risk in women following an inconclusive mammogram result (BI-RADS III or IV), which primarily occurs in women with dense breasts. The results provided by the test have demonstrated specificity of 98%+ in both women over and under the age of 50 making it a powerful tool to help guide decisions of whether to continue to monitor patients intermittently, or whether to advance immediately into a more expensive and invasive diagnostic such as a breast biopsy. With breast biopsies having been found to show a false-positive rate following diagnostic screening procedures as high as 71 percent in the United States according to the National Cancer Institute, the annual cost in biopsy procedures that might have been avoided is estimated to be \$2.18 billion. The Company sees a significant market opportunity for a breast cancer screening test for women under the age of 40 because current diagnostic tools do not recommend mammogram screening for this demographic. The dense breast population for which Videssa has been clinically validated also represents approximately 40% of mammogram recipients annually in the US.

Launched Phase 2 Clinical Trial of Its Antiviral 3CL Protease Inhibitor NLC-V-01 (Tollovir™) in Hospitalized COVID-19 Patients

The 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. 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 development of antiviral therapies against SARS-CoV-2 (the virus that causes COVID-19). Todos expects to provide interim data and to expand the study into India in the fourth quarter of 2021.

Receives FDA Certificate of Free Sale for New 5-Day Tollovid® Dosing Regimen

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.

Received Notice of Allowance from European Patent Office for Patent Application Covering Diagnosis of Cancer Using Proprietary Artificial Intelligence TBIA Immune Profiling Platform

The patent application specifically covers methods for capturing consistent data from infrared spectroscopy readers, as well as the application of various artificial intelligence algorithm development methods to the data. The ability of TBIA to make a diagnosis of cancer has first been applied to the detection of breast and colon cancers, where Todos Medical has received CE Marks in Europe paving the way for commercialization initially focused on TMB-2 (dense breast / inconclusive mammogram secondary screening) and TMB-1 (general breast cancer screening) cancer detection tests.

"We made significant strides in the second quarter to position Todos for future growth on several fronts, including receiving \$6.3 million in crossover investments led by Yozma Global Genomic Fund priced at \$0.0599 per share," stated Gerald E. Commissiong, President and CEO of Todos Medical. "On the business front, first and foremost, the acquisition of Provista gives us the ability to establish a commercial ready test addressing a multi-billion market opportunity. It also provides us with a CLIA/CAP lab to drive growth in COVID-related testing as well as expanding into other high-volume testing through our automation capabilities. Second, the launch of our Phase 2 trial for Tollovir as a COVID antiviral candidate is a potential game changer for our company and we are excited about our plans to further expand the trial into India later this year. The receipt of additional certificates of free sale for our Tollovid in the second and third quarter also bolsters our ability to capitalize on 3CL protease inhibition in the immune support market. Lastly, the forwarding of our TBIA patent portfolio in Europe helps solidify our IP while we continue to develop this important diagnostic solution. As we move through the second half of 2021, we are focused on ramping testing volume at Provista, growing revenue at our COVID distribution business, and continuing the development and commercialization of our antivirals, supplements and diagnostic solutions. We also continue to work to position the company to achieve an uplisting to a national stock exchange. We are confident that this strategy will enable us to achieve significant long-term value for our stockholders."

Financial Highlights for Q2 2021

Revenues: Total revenue in the second quarter of 2021 was \$1.7 million, a significant increase compared to revenue of \$32,000 in the second quarter of 2020. The increase in revenue was due to sales from the Company's COVID product distribution business.

Loss from Operations: The Company recorded an operating loss of \$(1,662,000) in the second quarter of 2021 compared to an operating loss of \$(1,719,000) in the second quarter of 2020. The decrease in net loss was a result of increased gross margin dollars coupled with decreases in R&D expenses and sales and marketing expenses, partially offset by an increase in general and administrative expenses.

Net Income: The Company recorded net income of \$3,390,000 in the second quarter of 2021 due to a \$5,171,000 increase in financing expenses, net, compared to a net loss of \$(2,585,000) in the second quarter of 2020. Net income per share in the second quarter of 2021 was \$0.01 on 575.9 million weighted average shares outstanding compared to the second quarter of 2020 where the Company incurred a net loss of \$(0.01) per share on 189.9 million weighted average shares outstanding.

Select Balance Sheet Items: The Company had cash of \$308,000 and trade receivables of \$1,792,000 as of June 30, 2021, compared to cash of \$935,000 and trade receivables of \$375,000 as of December 31, 2020. Total assets as of June 30, 2021, were \$17,258,000 compared to \$6,009,000 as of December 31, 2020. Shareholder deficit decreased to \$(8,999,000) as of June 30, 2021, compared to \$(11,001,000) as of December 31, 2020.

"While we achieved significant business milestones in the second quarter, we also witnessed several key improvements to our financial condition as well," said Daniel Hirsch, CFO of Todos Medical. "Our asset base was expanded significantly through our acquisition of Provista while our deficit decreased by \$2 million, with a significant portion of our outstanding debt being convertible into preferred equity upon the Company's uplisting to a national stock exchange. We expect further improvements to our balance sheet in the third quarter as we work to position the Company for a potential uplisting in the coming quarters."

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 2020, 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.

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TODOS MEDICAL LTD.**CONDENSED STATEMENTS OF OPERATIONS**

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

	Six months period ended June 30,		Three months period ended June 30,	
	2021	2020	2021	2020
	Unaudited		Unaudited	
Revenues	\$ 6,763	\$ 32	\$ 1,732	\$ 32
Cost of revenues	(4,148)	(11)	(913)	(11)
Gross profit	2,615	21	819	21
Research and development expenses	(643)	(569)	(239)	(465)
Sales and marketing expenses	(1,958)	(1,430)	(599)	(680)
General and administrative expenses	(3,204)	(925)	(1,643)	(595)
Operating loss	(3,190)	(2,903)	(1,662)	(1,719)
Financing income (expenses), net	(10,485)	(4,320)	5,171	(866)
Share in losses of affiliated companies accounted for under equity method, net	(492)	-	(119)	-
Net income (loss)	\$ (14,167)	\$ (7,223)	\$ 3,390	\$ (2,585)
Basic and diluted net income (loss) per share	\$ (0.02)	\$ (0.04)	\$ 0.01	\$ (0.01)
Weighted average number of ordinary shares outstanding attributable to ordinary shareholders used in computation of basic and diluted net income (loss) per share	585,225,006	164,423,927	575,898,572	189,945,607

CONDENSED CONSOLIDATED BALANCE SHEETSTODOS MEDICAL LTD.

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

	As of	As of
	June 30, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 308	\$ 935
Trade receivables	1,792	378
Inventories	1,704	536
Other current assets	123	601
Total current assets	<u>3,927</u>	<u>2,450</u>
Non-current assets:		
Investment in affiliated companies accounted for under equity method, net	658	745
Investment in other company	455	224
Property and equipment, net	2,596	1,999
Prepaid expenses	361	591
Goodwill	7,761	-
Intangible assets	1,500	-
Total non-current assets	<u>13,331</u>	<u>3,559</u>
Total assets	\$ 17,258	\$ 6,009
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Receivables financing facility, net	\$ -	\$ 1,306
Loans, net	2,756	1,672
Accounts payable	1,087	1,640
Deferred revenues	13	844
Other current liabilities	3,941	2,316
Liability for minimum royalties	296	291
Total current liabilities	<u>8,093</u>	<u>8,069</u>
Non-current liabilities:		
Convertible bridge loans, net	15,560	5,965
Derivative warrants liability, net	7	301
Fair value of bifurcated convertible feature of convertible bridge loans	2,077	2,500
Deferred taxes	315	-
Liability for minimum royalties	205	185
Total non-current liabilities	<u>18,164</u>	<u>8,951</u>
Shareholders' deficit:		
Ordinary Shares of NIS 0.01 par value each: Authorized: 1,000,000,000 shares at June 30, 2021 and December 31, 2020; Issued and outstanding: 607,760,492 shares and 376,335,802 shares at June 30, 2021 and December 31, 2020, respectively	1,765	1,059
Additional paid-in capital	50,684	35,211
Accumulated deficit	(61,448)	(47,281)
Total shareholders' deficit	<u>(8,999)</u>	<u>(11,011)</u>
Total liabilities and shareholders' deficit	\$ 17,258	\$ 6,009



Source: Todos Medical Ltd.