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Immunovaccine Announces Third Quarter 2016 Financial Results and Provides Corporate Update

HALIFAX, NOVA SCOTIA -- (Marketwired) -- 11/08/16 --

Immunovaccine Inc. ("Immunovaccine" or the "Company") (TSX:IMV)(OTCQX:IMMVF), a clinical-stage vaccine and immunotherapy company, today announced financial results for the third quarter ended September 30, 2016 and provided a corporate update.

"Our achievements during the third quarter of 2016 reinforced the strong progress that Immunovaccine has established across all three pillars that support the long-term success and value proposition for our DepoVax™-based pipeline," said [Frederic Ors, Immunovaccine's Chief Executive Officer](#). "In immuno-oncology, we continued to demonstrate growth and our commitment to developing new treatments for ovarian cancer. We advanced partnerships and showed steady clinical progress in this disease area, which is one of the most unmet medical needs in today's oncology landscape."

Third quarter highlights included:

- Announcing positive Phase 1/1b topline results for DPX-Survivac in ovarian cancer
- Dosing the first patient in the ongoing Phase 1b trial in collaboration with Incyte Corporation, which the Company believes to be one of the first clinical trials to assess triple combination therapies in ovarian cancer
- Terminating the licensing agreement with Immunotope Inc. as a means to reallocate resources from the DPX-0907 candidate to accommodate planned growth for other immuno-oncology programs
- Publication of preclinical research on the effects of combining DepoVax™-based vaccines and anti-PD-1 therapies in *The Journal for ImmunoTherapy of Cancer*
- Announcing positive Phase 1 results for its DPX-RSV candidate, which also marked the first infectious disease clinical demonstration of safety and immunogenicity for a DepoVax™-based compound
- Presentations at several prestigious scientific conferences, showcasing the depth and breadth of the DepoVax™-based pipeline in applications that span from malaria and RSV to immuno-oncology checkpoint inhibitor combinations

"We achieved a major milestone in our ongoing collaboration with Incyte Corporation, dosing the first patient in our Phase 1b trial evaluating the safety and immunogenicity of what we believe to be the first triple combination therapy in patients with recurrent ovarian cancer, which includes DPX-Survivac, Incyte's IDO1 enzyme inhibitor epacadostat, and low-dose cyclophosphamide. We are currently planning to have the first data readout from this study in Q1 2017."

In the third quarter, Immunovaccine also announced positive topline data in its Phase 1/1b trial evaluating DPX-Survivac in combination with cyclophosphamide in ovarian cancer. The expanded data set reinforced earlier results that indicated that DPX-Survivac was well tolerated, with no unexpected treatment-related serious adverse events (SAEs) and that it could generate a relevant, sustained immune response. Although the trial was not specifically designed to assess progression-free survival (PFS), trial data indicated that there may be a correlation between the immune response and PFS. In addition, researchers determined an optimal dosing schedule to be used in future trials evaluating DPX-Survivac in this indication.

Mr. Ors stated, "These findings are quite significant for DPX-Survivac because we believe that they reinforce the utility and inherent value in its novel mechanisms of action. These data add to the growing body of research indicating the positive effects that DepoVax™-based agents have on increasing circulating T cells and tumor susceptibility to additional immune therapies, including checkpoint inhibitors. The clinical data thus far, we believe, advantageously position DPX-Survivac as an optimal component of future combination therapies."

Findings related to combination therapies were reinforced in a preclinical data presentation this September at the 2016 CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference. Researchers presented data on the effects of a DepoVax™-based agent in combination with cyclophosphamide on tumor progression and the tumor microenvironment (TME). Researchers concluded that vaccine immunotherapy could enhance anti-PD-1 therapy by promoting the activity of antigen-specific T cells within the TME. These findings were published in the [*Journal for ImmunoTherapy of Cancer*](#) in October 2016.

"We believe that these findings provide further support for advancing clinical development based upon effective T cell activation therapies in combination with checkpoint inhibitors, and we are in active discussions with collaborators in this space," said Mr. Ors.

"With an eye towards focusing our immuno-oncology programs on those best-positioned to maximize the advantages of our DepoVax™-based system and the needs of our current and future collaborators, we terminated our agreement with Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome for an investigator-lead planned trial for DPX-Survivac in patients with glioblastoma. We also began the process of terminating the licensing agreement with Immunotope Inc. for the use of certain patented antigens. These antigens had been used specifically for our DPX-0907 program, which we have opted to discontinue" noted Mr. Ors.

"The second pillar of our business strategy focuses on leveraging our DepoVax™-based technology in the infectious disease arena," said Mr. Ors. "RSV continues to be a large unmet medical need, particularly among vulnerable populations like the elderly, very young and immuno-compromised. Recent industry setbacks in developing a vaccine to address this infection are indicative of the challenges facing clinicians who are working to address its debilitating effects."

In July, Immunovaccine announced positive interim data, which was followed up shortly after the quarter ended with topline data, from its Phase 1 trial in RSV evaluating the safety and immunogenicity of the DPX-RSV vaccine candidate.

"These results yielded three significant points that highlight the value of our DPX-RSV program," stated Mr. Ors.

1. "Achieving a key safety milestone-namely demonstration of a tolerable safety profile with no significant adverse events;
2. Demonstrating relevant, antigen-specific immune responses at least six months after the last vaccination in both low-dose (8/8 participants) and high-dose (7/8 participants) cohorts; and,
3. Highlighting the advantages of our proprietary mechanism of action and targeting the SH antigen of RSV, which are unlike other approaches that may not provide enough protection against RSV and its complications."

Currently, there is no marketed vaccine to prevent RSV.

"To the best of our knowledge," said Mr. Ors, "Immunovaccine has the only program targeting the SH antigen to address RSV, and we hold exclusive worldwide licenses on applications that target the SH ectodomain antigen in RSV. This puts us in a position, potentially, to both bring much-needed benefit to address an unmet public health need, and drive value for our investors and potential future collaborators via a novel, proprietary methodology to combat RSV."

In addition, the Company's infectious disease-related development programs yielded data presentations at several industry conferences. Researchers detailed findings of the novel DPX-RSV program at the International Respiratory Syncytial Virus Symposium (RSV16), the World Vaccine Congress, and IDWeek. In addition, shortly after the quarter ended, Immunovaccine collaborators at the University of Edinburgh announced positive preclinical data on DepoVax™-based malaria vaccine research at the World Vaccine Congress. While there are multiple pathogens and forms of malaria, this study focused specifically on the type of infection most likely to result in death, in which infected red blood cells stick together with uninfected red cells, forming clumps within small blood vessels that block blood flow. This process, known as rosetting, can result in hypoxia, organ damage, and, in some cases, death.

Researchers found that novel targets, when formulated in the DepoVax™ targeting platform, generated strong, sustained, antibody responses that could prevent, after a single injection, the 'rosetting' process.

"Severe malaria continues to present a significant worldwide health concern, and we believe that a vaccine that can address its most virulent forms could positively impact global malaria-related mortality rates," said Mr. Ors. "For Immunovaccine, this further supports the value proposition that DepoVax™ is emerging as an ideal enabling agent for novel treatments being developed to address some of the world's most challenging infectious diseases.

"On the corporate front-the third pillar of Immunovaccine's value proposition-we started off this quarter with a strong financial position, coming off of an \$8M equity financing that occurred just before the quarter started. We also continued to expand the audience of potential investors for Immunovaccine, participating in the BIO Investor and Rodman & Renshaw conferences."

Shortly after the quarter ended, Immunovaccine announced the departure of its chief

financial officer, Kimberly Stephens. The Company is currently working with the Board on the process of identifying a new CFO, and Ms. Stephens will continue to work with Immunovaccine through December 2016 while her successor is fully transitioned into the position.

"In addition," said Mr. Ors, "we are very proud to have recently named our first-ever chief medical officer (CMO) as Dr. Gabriela Rosu joins our leadership team. Dr. Rosu brings to Immunovaccine more than 15 years of broad clinical and pharmaceutical industry experience that spans the entire value chain of pharmaceutical development, from early phase discovery to post-marketing commercialization. The clinical and commercial experience that Gabriela brings to our team will be instrumental in preparing for our expansion and validates the potential of our platform and product candidates. We are thrilled to welcome her to our team, and believe that the depth and breadth of her medical knowledge, as well as her industry track record, are tremendous assets to our organization."

Looking forward, Mr. Ors noted, "While cancer and infectious disease may present as very different illnesses, they share the process of continually evolving, often outpacing even the newest treatment options that our industry can bring to market. This third quarter, while our clinical programs continued to progress, we were also able to expand our research and development activities, including research in malaria and neoepitope immunotherapies, ensuring that our DepoVax™-based platform is well positioned to be a long-term force in immuno-oncology and infectious diseases. We expect continued progress along these fronts for the balance of 2016 and into 2017. We are also looking forward to advancing the programs with our current collaborators, and to announcing new partnerships that will drive value to our investor base, and support our goal of bringing novel medicines to market quickly and safely."

Q3 2016 Financial Results

The Company prepares its unaudited interim condensed consolidated financial statements in accordance with Canadian generally accepted accounting principles as set out in the Chartered Professional Accountants of Canada - Accounting Part I ("CPA Canada Handbook"), which incorporates International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The net loss and comprehensive loss of \$1,899,000 for the quarter ended September 30, 2016 ("Q3 Fiscal 2016") was \$105,000 lower than the net loss and comprehensive loss for the three months ended September 30, 2015 ("Q3 Fiscal 2015"). This relates mainly to a \$361,000 decrease in research and development costs, a \$97,000 decrease in business development costs, offset by a \$61,000 increase in general and administrative expenditures, a decrease in revenue of \$65,000, a \$32,000 increase in accreted interest, and an impairment loss of \$195,000.

For Q3 Fiscal 2016, the Company reported total R&D expenses of \$763,000, net of government loans and assistance of \$49,000 and investment tax credits of \$61,000. This represented a \$361,000 decrease of net research and development expenses over Q3 Fiscal 2015. General and administrative expenses of \$686,000 were reported for Q3 Fiscal 2016 compared to \$625,000 for Q3 Fiscal 2015. Total business development expenses of \$118,000 in Q3 Fiscal 2016 represented a decrease of \$97,000 compared Q3 Fiscal 2015. The impairment loss of \$195,000 relates entirely to the termination of Immunovaccine's

exclusive world-wide license with Immunotope for the use of patented antigens in its therapeutic cancer vaccine candidate, DPX-0907.

At September 30, 2016, Immunovaccine had cash and cash equivalents of \$7,908,000 million and working capital of \$7,652,000 million as compared to \$3,842,000 million in cash and \$3,283,000 million in working capital at December 31, 2015.

As of September 30, 2016, the number of issued and outstanding common shares was 106,911,508. On September 30, 2016, the number of stock options outstanding was 6,456,487 and the number of outstanding warrants was 8,146,908.

Immunovaccine's unaudited interim condensed consolidated financial statements for September 30, 2016, filed in accordance with IFRS, and the management discussion and analysis (MD&A), will be available at www.sedar.com.

About Immunovaccine

Immunovaccine Inc. is a clinical-stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer and infectious diseases. Immunovaccine develops cancer immunotherapies and infectious disease vaccines based on the Company's DepoVax™ platform, a patented delivery agent that provides controlled and prolonged exposure of antigens and adjuvant to the immune system. Immunovaccine has advanced two T cell activation therapies for cancer through Phase 1 human clinical trials and is currently conducting a Phase 1/1b study with Incyte Corporation assessing lead cancer therapy, DPX-Survivac, as part of a triple combination therapy in ovarian cancer, as well as a Phase 2 study in recurrent lymphoma. The Company is also advancing an infectious disease pipeline, including innovative vaccines for respiratory syncytial virus (RSV), and currently has clinical projects ongoing to assess the potential of DepoVax™ to address malaria and the Zika virus. Connect at www.imvaccine.com.

Immunovaccine Forward-Looking Statements

This press release contains forward-looking information under applicable securities law. All information that addresses activities or developments that we expect to occur in the future is forward-looking information. Forward-looking statements are based on the estimates and opinions of management of the Company on the date the statements are made. However, they should not be regarded as a representation that any of the plans will be achieved. Actual results may differ materially from those set forth in this press release due to risks affecting the Company, including access to capital, the results and successful completion of clinical trials and receipt of all regulatory approvals. Immunovaccine Inc. assumes no responsibility to update forward-looking statements in this press release except as required by applicable law.

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