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Northwest Biotherapeutics Acquires Flaskworks

Breakthrough Automation Technology For Cell Therapy Products
To Enable Scale-Up of Production Volumes and Reduction of Production Costs

BETHESDA, Md., September 1, 2020 - Northwest Biotherapeutics (OTCQB: NWBO) ("NW Bio"), a biotechnology company developing DCVax® personalized immune therapies for solid tumor cancers, today announced that the Company has acquired Flaskworks, a company that has developed a breakthrough system to close and automate the manufacturing of cell therapy products such as DCVax®.

Flaskworks was previously owned by its technical founders and Corning Incorporated. The technical team from Flaskworks has joined NW Bio as part of the acquisition.

It is anticipated that the Flaskworks system will enable substantial scale-up of production volumes of DCVax products and substantial reduction of production costs.

To date, the manufacture of immune cell therapies (including T cell therapies and others) has involved two major challenges. First, the manufacturing processes involve "open" steps in which the product is open to the air in the manufacturing suite. This necessitates extremely expensive "clean room" facilities with specialized infrastructure and specialized operating systems for sterile air and water, and personnel working in sterile lab suits ("space suits"). Second, the manufacturing processes are mostly manual processes – in essence, hand crafted artisan processes by highly skilled technicians working under sterile conditions.

These factors have made the manufacturing of immune cell therapies (such as T cells) very costly, and greatly limited the number of such therapies that can be produced. There simply are not enough of the specialized clean room facilities, not enough highly skilled artisan technicians, and each technician can only produce limited amounts of products.

The Flaskworks system is designed to fundamentally change the manufacturing process from artisan hand work to assembly line-like automation. As such, the Flaskworks system is designed to enable the scale-up to far greater production volumes. Technicians will oversee the automated systems (potentially multiple systems per technician) rather than making the products themselves.

The Flaskworks system is also expected to significantly reduce production costs: turning "open" steps in the manufacturing process into "closed" steps, in which the product is not open to the air in the manufacturing suite, removing the need to build and operate the extremely costly clean room suites for those processes, and removing the need for personnel to work in sterile lab suits. This will greatly reduce the DCVax-L production costs.

The buildout of the Sawston, UK facility has purposely been designed to proceed in phases, as modules, both for efficiency in the timing of capital costs and to allow flexibility in operations and usage. Implementation of the Flaskworks system will enable certain phases of the buildout to be simplified and streamlined.

The existing manufacturing process for DCVax-L products already takes a practical and economical approach by using a batch manufacturing process combined with special cryopreservation technology. The full set of doses for a patient, for as much as 3 years of treatments, are all produced in a single 8-day manufacturing batch, and then are stored frozen in single doses. The freezing technology has been validated and was used throughout the Company's Phase 3 trial. This makes DCVax-L an off-the-shelf product for the whole treatment period after the one-time manufacturing batch, while also being a fully personalized product.

The Flaskworks system will follow the same batch-manufacturing process – doing so in a "closed" and automated manner.

Certain optimization work will be required so that the Flaskworks system will produce DCVax-L products with characteristics equivalent to the products made by the current DCVax-L manufacturing processes. This will then need to be confirmed by comparability studies. The Flaskworks technical team will work with NW Bio's contract manufacturers to accomplish this. In the meantime, the Company's DCVax products will continue to be made through the existing processes.

The acquisition of Flaskworks was executed and closed on August 28, 2020. The total purchase price was approximately $4.33 million, of which $1.65 million was paid in cash at closing, up to $2.01 million will be paid in stock subject to milestone-based vesting, and $0.67 million will be paid in either cash or stock, or a combination thereof, within 120 days after the closing.

The acquisition includes both intellectual property owned by Flaskworks and a license of additional intellectual property from Northeastern University.

Although a number of companies have developed and are continuing to develop automated machines for certain cell therapy production processes, those machines have certain drawbacks. For example, they typically try to handle a variety of cell types and have not been optimized for a particular cell type, such as dendritic cells. In contrast, the Flaskworks system has been developed and tailored specifically for immune cells such as dendritic cells.

Linda Powers, NW Bio's CEO commented, "We believe that our DCVax platform technologies are potentially applicable to all types of solid tumor cancers, which comprise the vast majority of all cancers. We are working to build the infrastructure and systems that can enable the scale-up of production to such volumes – and can do so at a price level that will be affordable for widespread use of DCVax treatments."

"The phased buildout of our Sawston, UK facility and now our acquisition of Flaskworks are major building blocks towards achieving these goals. These steps, along with others in process, have been years in the making to reach fruition at the same time as we are reaching the results of our Phase 3 clinical trial of DCVax-L for Glioblastoma."

About Northwest Biotherapeutics

Northwest Biotherapeutics is a biotechnology company focused on developing personalized immunotherapy products designed to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and on a cost-effective basis, in both North America and Europe. The Company has a broad platform technology for DCVax® dendritic cell-based vaccines. The Company's lead program is a 331-patient Phase III trial of DCVax®-L for newly diagnosed Glioblastoma multiforme (GBM). GBM is the most aggressive and lethal form of brain cancer, and is an "orphan disease." The Company is also pursuing development of DCVax®-Direct for inoperable solid tumor cancers. It has completed a 40-patient Phase I trial, and is preparing for Phase II trials. The Company previously conducted a Phase I/II trial with DCVax-L for advanced ovarian cancer together with the University of Pennsylvania.

Disclaimer

Statements made in this news release that are not historical facts, including statements concerning future treatment of patients using DCVax and future clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "expect," "believe," "intend," "design," "plan," "continue," "may," "will," "anticipate," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results may differ materially from those projected in any forward-looking statement. Specifically, there are a number of important factors that could cause actual results to differ materially from those anticipated, such as risks related to the Company's ability to enroll patients in its clinical trials and complete the trials on a timely basis, uncertainties about the clinical trials process, uncertainties about the timely performance of third parties, risks related to whether the Company's products will demonstrate safety and efficacy, risks related to the Company's ongoing ability to raise additional capital, and other risks included in the Company's Securities and Exchange Commission ("SEC") filings. Additional information on the foregoing risk factors and other factors, including Risk Factors, which could affect the Company's results, is included in its SEC filings. Finally, there may be other factors not mentioned above or included in the Company's SEC filings that may cause actual results to differ materially from those projected in any forward-looking statement. The Company assumes no obligation to update any forward-looking statements as a result of new information, future events or developments, except as required by securities laws.

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