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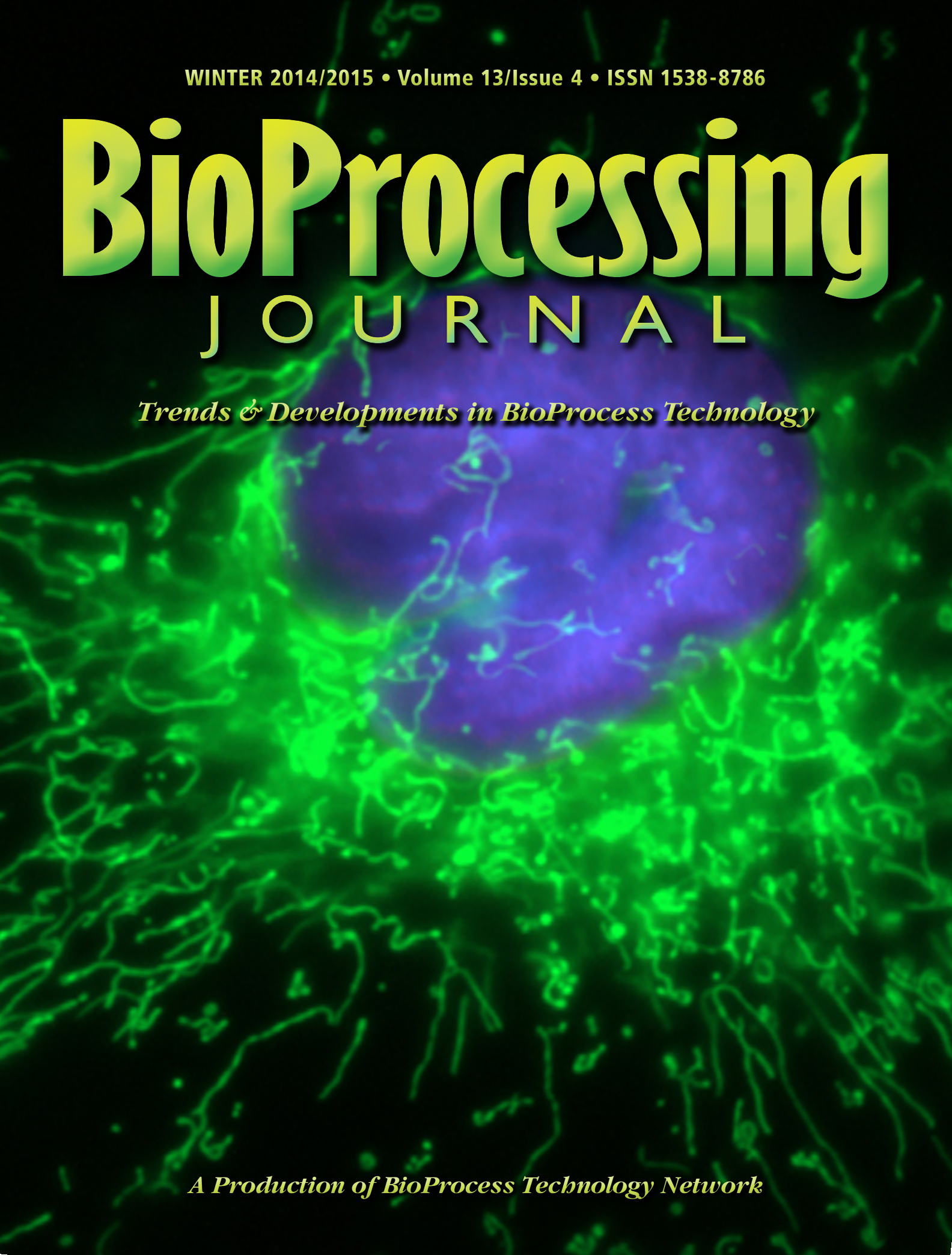
Trends & Developments in BioProcess Technology



A Production of BioProcess Technology Network

From the Editor-in-Chief

No, I'm not going to write about my disdain for M&As in this issue. Thankfully, recent market fluctuations have made them less attractive, and we can see more firms committed to building the businesses they already have, and developing strategic partners instead of acquisition targets.

For this issue, I want to address the developments that may mean we are entering some lofty times in the biotech industry. One of the beacons of light has been the licensing of an adeno-associated viral (AAV) vector in Europe, with US licensing activities well underway. And an aspect that makes this product more remarkable is that the AAV was produced with baculovirus technology, which may become the preferred route to making AAV.

Then in the US, an influenza vaccine produced with baculovirus technology has been licensed, and a second firm is poised to have its flu vaccine approved. In addition, both firms are working on Ebola vaccines which will be produced with this technology. Furthermore, it appears that the Biomedical Advanced Research and Development Authority (BARDA) has shown considerable interest in the potential of baculovirus expression systems for the ever-changing list of pandemic disease vaccines, as well as bioterror countermeasures that it may need quickly. BARDA has shown a renewed interest in plant-derived vaccine antigens and bacterial antitoxins.

The primary viral vector in clinical trials is currently AAV, with a growing number of serotypes. However, there is a lot of activity with lentiviruses, and the industry may start working on a reference material that can be used to validate internal reference materials and assays. Much of the lentiviral activity appears to involve HIV and herpes, but any number of oncolytic viral vectors could be entering clinical trials in the next couple of years. In addition, there seems to be some renewed interest in the use of adenovirus, including two malaria vaccines in the Washington, DC area that I've noted. And while less frequent, there are some applications underway with the use of retroviruses.

There has also been a considerable amount of success with cellular therapies—despite the demise of Dendreon, which shall forever be known for its heroic role in getting the first cellular cancer vaccine licensed. This product provides a roadmap for other firms to follow and considerable precedent that regulators can use for future products. Now there is so much accumulated experience that a number of cellular cancer vaccines could be licensed soon.

Also in the cellular therapy realm, patient T cells are being genetically engineered to produce chimeric antigen receptors (CARs) on their surfaces. These receptor proteins allow the T cells to recognize specific antigens on tumor cells where they attach and kill the cells. This technology is an extension of the activated T cell therapy work pioneered by Steven Rosenberg at the National Cancer Institute (NCI), but it has been much more effective.

Another cell therapy advancement is with adult mesenchymal stem cells which can be differentiated to regenerate essentially any type of tissue. The use of microcarriers and other devices, which provide the surface area needed to propagate these anchorage dependent cells, has really helped to advance this technology. Success stories appear on a regular basis, including experiments to regenerate nerves.

Then coupled with all the work on antibody-drug conjugates (ADCs), which have become far more feasible with better ways of linking the drugs to the antibody molecules, there is a tremendous amount of activity building for new biologics. Hopefully we'll see more money being invested in R&D infrastructure and personnel to replace what has been dismantled during the years of M&A mania.

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