

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA



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There's a saying that "Expression systems aren't everything, but everything is nothing without a good expression system"

Expression systems encompass the technologies, biological materials and associated knowhow, needed to genetically modify organisms for the manufacture of recombinant proteins and other products. For biosimilars, the future of affordable healthcare, there are many novel expression systems that offer significant improvements over the most common production hosts today (like the mammalian, bacterial and yeast). The new technologies are aiming to reduce the investments and the production and development costs in order to enable the rapid delivery of protein products into clinical development and commercialization. Biosimilar manufacturers need to develop these new technologies in order to increase expression system yields to enable use of smaller bioreactors, reduce downstream freezer (storage) capacity and lower cost. In addition, those new technologies will also be ready to challenge the new development of personalized medicine space. Dyadic's Patented C1 Expression System is based on its recombinant host production organism *Myceliophthora thermophila*, a filamentous fungus that has been nicknamed C1. The recombinant C1 organism has demonstrated expression of much higher levels of secreted proteins when compared to the best commercial yeast host production organisms. The C1 expression system is capable of expressing extremely high levels of secreted protein, upwards of 100 g/l, with 80% purity (or ~80 g/l) of a targeted heterologous protein of interest. By comparison the highest levels reported for yeast expression systems such as *Pichia pastoris* and *Saccharomyces cerevisiae* are reaching about 25% of the C1 expression levels. Dyadic is currently developing the C1 expression system to meet the biologics and biosimilar requirements, since this technology has several unique advantages over the current production host systems as 1) No royalty stacking as our versatile genetic tools that enable efficient genetic manipulation and rapid selection procedure are solely owned by Dyadic. 2) C1's very high productivity is expected to lead to dramatic reductions in fermentation and downstream Capex, as well as Opex. 3) Efficient protein expression of high value proteins that include heterologous genetic sources. 4) The expressed protein can be secreted from the cells to the media at very high concentrations and purity, which significantly reduces the purification efficiency and cost, as well as the associated downstream freezer capacity. 5) C1 is proven in commercial-scale production that offers flexibility in manufacturing capacity from <1m³ up to 500m³ fermenters. 6) C1 proteins are not over-glycosylated, as found in yeast, and have a structure that make the humanization of the glycosylation pattern of mammalian protein feasible. 7) Acquired Generally Regarded As Safe ("GRAS") certificate recognized by the FDA and 8) Our approach in further developing the commercially proven C1 technology for the production of therapeutic proteins in general and for Biosimilars in particular will be presented.

Biography

Mark A Emalfarb is known as a Pioneer of the stone-washed blue jean industry and a Member of the Iowa Hawkeye NCAA Championship wrestling teams. He is the CEO of Dyadic (OTCQX: DYAI) and founded it in 1979. Since then, he has successfully led and managed the evolution of Dyadic from its origins in the stone-washing business to the discovery, development, manufacturing and commercialization of specialty enzymes and other proteins, including human vaccines derived from DNA which are used in various applications to help feed, fuel and heal humankind. He is an inventor of over 25 US and foreign biotechnology patents and is the architect behind the creation and development of Dyadic's revolutionary patented C1 Protein Expression System, based on a recombinant *Myceliophthora thermophile* fungus. He is also responsible for the formation of several strategic researches, development, manufacturing and marketing relationships with US and European global partners such as Sanofi Pasteur (human vaccines), BASF (food, feed and other enzymes), Abengoa (renewable non-food biofuels) and others.

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