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Quicker, cheaper, better is Dyadic motto as it eyes more animal health C1 cell line partners

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Founded in 1979, Dyadic International has applied its enzyme-based innovation to multiple industries. Now, the firm is turning its attentions more to the animal health space. Animal Pharm editor Joseph Harvey spoke to the company's founder and chief executive Mark Emalfarb, as well as chief commercial officer Mathew Jones, to find out more.



Dyadic International's main mission in the animal health market is to make companies aware of the R&D and biomanufacturing advantages its C1 cell line can offer.

The firm's C1 technology is an expression system based on the fungus *Myceliophthora thermophila* that can be used for gene discovery and development, as well as to produce large amounts of low-cost enzymes and other proteins.

Mark Emalfarb said: "Penicillin is a fungus that was discovered by accident. The discovery of our fungus was serendipitous too. Through random mutagenesis, we've been on a 25-year journey working with this very productive cell line, which has become an extremely disruptive technology."

While Dyadic is targeting a range of industries, the company believes its technology can be particularly beneficial in the development of veterinary biotherapeutics.

Mr Emalfarb said the company's platform has the potential to remove a critical bottleneck in protein development and manufacturing processes that are harming the animal health industry's ability to bring high-quality affordable biologics to market in a timely fashion. The C1 technology provides a safe and

efficient expression system that can accelerate the development and production of biologics at flexible commercial scales, in greater volumes and at lower costs.

Mark Emalfarb: "We like to think our genetic toolbox is unsurpassed in biotech. Our system is cleaner, it reduces spend and cuts development time."

Florida-based Dyadic believes its patented technology helps to overcome numerous inadequacies of existing expression technologies currently used for gene discovery, product development and large-scale affordable biomanufacturing. The firm claims its fully programmable C1 system is one of very few commercially available solutions that can efficiently uptake genes and develop scalable industrial processes to produce large volumes of affordable enzymes and other protein products.

"The cell line can do things that others can't because of its high productivity level," said Mr Emalfarb. "It's all about enablement and cost of goods. We can provide massive upstream production advantages, as well as reducing CapEx and OpEx. Certain data generated in one or more of our research collaborations showed potentially better immune response at a lower cost."

Dyadic had previously licensed the C1 system on a non-exclusive basis to "some of the world's largest and most renowned industrial biotechnology companies, such as Abengoa, BASF and Codexis/Shell Oil". Then, at the end of 2015, the firm sold the rights to the use of its technology in the industrial sector to DuPont for \$75 million in cash.

After this deal, the company shifted its sights to the biopharmaceutical space. DuPont granted Dyadic co-exclusive rights to the C1 technology and the exclusive sub-license rights for use in human and animal pharmaceuticals. At was around this time when Mr Jones joined the company.

He said Dyadic is hoping to combine the proceeds from the DuPont transaction with external funding to ramp up further optimization of the C1 technology and seek partners in the animal health sector.

ZAPI insight

Dyadic is also part of several research consortiums, including the Zoonotic Anticipation and Preparedness Initiative (ZAPI). This project also features Boehringer Ingelheim Animal Health and AstraZeneca. ZAPI aims to bring together experts in human and animal health to create technologies that will facilitate a fast and coordinated response to new infectious diseases.

Based on the successful C1 fermentation results of the Schmallenberg virus, with a yield of 17 times the initial targeted expression level, animal studies using the C1-produced ZAPI antigen were conducted.

In December, Dyadic received positive preliminary results from the ZAPI animal studies and expanded its research collaboration with ZAPI to express two additional proteins. Preliminary results from the animal studies indicated that Dyadic's C1 antigen demonstrated very strong performance in protecting both cattle and mice from the Schmallenberg virus. As a result, ZAPI expanded the scope of the firm's involvement in the program and Dyadic expects to receive additional funding from the ZAPI consortium in support of production of the two additional targets.

"We are very pleased with the initial promising results from this study and expect the final results to be published during the second quarter of 2020," said Mr Emalfarb. "We are also excited to be working on two

additional proteins for the animal health market where we already have ongoing collaborations with two of the top four animal health companies."

Commercial model

"We're not a binary deal company," Mr Jones told *Animal Pharm*. "We're agnostic to the therapeutic and species in so much as our workhorse cell line can express genes of interest in high amounts regardless of the disease target. We want to capitalize on our productive C1 cell line and to have Dyadic better recognized as a partner of choice in animal health.

"We like to think our genetic toolbox is unsurpassed in biotech. Our system is cleaner, it reduces spend and cuts development time. Animal health companies don't have access to this kind of flexible manufacturing capability for vaccines or antibodies, such as monoclonal antibodies (mAbs)."

Mr Emalfarb added: "We have a whole library of C1 cells in place for companies to explore and find out which C1 cell line works best for them."

While the C1 technology is applicable to animal health's leading manufacturers, Mr Jones said he also hoped smaller businesses would become Dyadic clients as well.

"If smaller companies can't afford a licence to the C1 technology, then we are willing to explore working with them on terms that suit both of us," Mr Emalfarb explained. "We're flexible and we're looking to create a situation where it is win-win for both companies."

In fact, the firm is already working with VLPbio – a Spanish start-up that has a pipeline of immunotherapeutic vaccines based on chimeric virus-like particles – and Australian companion animal therapeutic developer Novovet. As a part of the collaboration, Dyadic gained equity in Novovet.

Mr Emalfarb said two of the global leaders in the animal health industry are currently test-driving the C1 platform. Dyadic aims to use research-focused licences as a way of segueing into larger partnerships.

He remarked: "I think our model is unique. We believe we have the answers to several problems and C1 offers flexible industrial scalability at lower cost of biomanufacturing. We also may offer a quicker path to market than certain other expression systems. There might be many projects that animal health companies might have shelved because they weren't getting high enough productivity and/or good immunogenicity. They need the best cell lines. If they are willing to take two steps back, we may be able to help them take 10 steps forward."

Mr Jones added: "Here at Dyadic, we are speaking with a wide range of animal health companies. However, those larger firms need to negotiate through many layers of red tape and are looking for experience on alternative cell lines.

"We are working successfully in this process and continue to encourage them to look outside of their comfort zone and consider new alternative and more powerful cell lines such as C1. That decision can take a while in this conservative environment. However, since the C1 expression and immunogenicity data is looking compelling we are starting to make very good progress.

"We want to fight for change and convince these companies and the biopharmaceutical industry there is a world outside their own R&D systems and the existing cell lines – the status quo might not be good enough. We want to positively disrupt this space and bring affordable healthcare options to animals, farmers and pet owners, while increasing margins at the bioprocessing firms."