

Alabama Company Improves the Delivery of Protein Therapies

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From antibodies to protein-based vaccines and hormone treatments, protein therapeutics are growing in popularity and sophistication. But for these therapies to be effective, the correct amount must be absorbed at the right place in human body. To solve this difficult problem, pharmaceutical developers must make sure proteins are soluble so they can be delivered and circulate in liquid form.

To reduce the substantial time and money often required to run dozens of solubility tests, University of Alabama biochemist Lawrence DeLucas, along with his colleague, Wilbur Wilson at the University of Mississippi, devised a method to streamline the process.

Using a small university grant, the team built a prototype device that could quickly and efficiently measure a protein's solubility. The technology is based partially on understanding how much a protein sticks to itself when dissolved in liquid and partially on an artificial neural network. A small tube is lined with a sample of a protein. Then the same protein is dissolved in liquid and passed through the coated tube. The amount of time it takes the dissolved protein to pass through the tube indicates its level of self-stickiness, which can be used to determine its solubility. The neural network uses the data to determine the ideal combination of additives that will make the protein soluble and stable – also referred to as the therapy's formulation.

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Soluble Biotech

200 River Hills Business Park
Suite 250
Birmingham, AL 35242

State-District

AL-6

Technology

Diagnostic

Primary Institute

General Medical (NIGMS)

Project Details from NIH RePORTER

[Soluble Biotech](#)

Contact

Lawrence Delucas
ldelucas@solublebiotech.com

solublebiotech.com

“I realized there was commercial value in this technology and that led me to want to form a company,” continues DeLucas. After patenting the method, Wilson and DeLucas founded Soluble BioTech in 2008 with the goal of reducing the time and money pharmaceutical companies spend making their formulations soluble and stable.

When the team realized the prototype they had built wouldn’t accommodate services for multiple pharmaceutical and biotech companies, they applied for a Small Business Technology Transfer (STTR) grant through the National Institute of General Medical Sciences. The Phase I and II grants allowed the company to build the faster, automated machines that they use today. DeLucas says receiving the grants also provided confidence in their technology, which helped them obtain a million dollars in venture capital as well as multiple contracts with pharmaceutical companies.

A second STTR grant enabled the company to incorporate membrane proteins into their workflow, which are fat-soluble and therefore often difficult to combine with liquids. DeLucas says the success of the project helped support a grant from the Cystic Fibrosis Foundation.

The company has worked with more than 30 pharmaceutical and biotech companies. In 2020, Soluble BioTech was acquired by Predictive Oncology, a public company (NASDAQ: POAI) that offers a suite of solutions for oncology drug development from early discovery to clinical trials. Now under the POAI name, they have a Good Manufacturing Practice facility that offers manufacturing capabilities to pharmaceutical companies for phase 1 clinical trials. In addition, they sell hundreds of protein solubilization kits each year.

