

Anaptys Biosciences Inc.

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Summary: According to the CEO of Anaptys Biosciences, therapeutic antibodies will continue to be the single largest growing segment in pharmaceuticals, but the number of companies providing solutions in this area is decreasing following a number of acquisitions. Anaptys will fill the gap with its somatic hypermutation technology platform for therapeutic antibody discovery and optimization. The platform replicates the natural process of mutagenesis occurring in B cells as part of the immune response, involving steps of immunoglobulin recombination, mutation, affinity maturation and selection.

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Anaptys Biosciences Inc.

Antibody discovery and protein optimization

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Contact: Tom Smart, Chairman & CEO

Industry Segment: Biotechnology

Business: Developing therapeutic antibodies using somatic hypermutation

Founded: 2005

Founders: William Boyle, PhD, President & CSO; Andrew Cubitt, PhD, VP, Business Development; Kevin J. Kinsella (Avalon Ventures); Nick Lydon, PhD (Granite Biopharma)

Employees: 12

Financing: \$3 million

Investors: Avalon Ventures

Board of Directors: Tom Smart; William Boyle; Nick Lydon; Kevin J. Kinsella; R. Scott Greer (Numenor Ventures)

Scientific Advisory Board: Michael Neuberger, PhD (Medical Research Council); Matthew Scharff, MD (Albert Einstein College of Medicine); Matthias Wabl, PhD (UCSF School of Medicine)

La Jolla-based **Anaptys Biosciences Inc.** is using its somatic hypermutation technology platform for therapeutic antibody discovery and optimization. According to chairman and CEO Tom Smart, therapeutic antibodies will continue to be the single largest growing segment in pharmaceuticals. "There is a high demand for generating therapeutic antibodies, but the number of companies providing solutions in this area is decreasing following a number of acquisitions, such as **MedImmune Inc.**'s recent acquisition by **AstraZeneca PLC** and **Eisai Co. Ltd.**'s purchase of **Morphotek Inc.** [W#200710064] [W#200710046] Those platforms that are left are often unavailable as they are licensed on an exclusive basis and the first movers in antibodies have locked up many of the best-known and validated targets.

"When I worked as a consultant at Avalon Ventures, I saw the concept of using a somatic hypermutation technology platform for the generation of therapeutics as a merger of good IT, technology, and business," explains Andrew Cubitt, Anaptys co-founder and VP of business development. The company's somatic

hypermutation-based platform, Omnitope-SHM, is based on patents licensed exclusively from the UK's **Medical Research Council** and the **Albert Einstein College of Medicine at Yeshiva University**.

The platform replicates the natural process of mutagenesis occurring in B cells as part of the immune response, involving steps of immunoglobulin recombination, mutation, affinity maturation, and selection. Omnitope-SHM incorporates recombinant libraries of fully human antibody genes, a vector system using somatic hypermutation technology to evolve and optimize the antibodies, and a rational epitope selection methodology to select optimized antibody candidates. Each round of selection, expansion, and evolution refines the library so that the library is increasingly composed of antibodies that meet in-house or partners' design goals.

The platform allows the creation of new antibodies as well as the improvement of existing ones, in a shorter timescale and with reduced resources because the company's platform harnesses somatic hypermutation for antibody evolution and optimization. The platform also allows for the evolution and selection of antibodies based on multiple parameters, such as binding to both human and rodent forms of the target to support the use of animal models. President and CSO William Boyle sums up the platform technology as, "a proprietary library of bivalent, full length, fully human antibody genes that are evolved in an unconstrained and most human-like manner using a mammalian cell-based system and selected across multiple parameters using a high throughput system."

According to Boyle, the advantages of the system include the generation of antibodies that are functional and stable, and as they are evolved in a "human-like" manner, they have a reduced risk of producing an immune response in the recipient. The platform is not subject to the limitations of in vivo immunization techniques, such as mouse immunization, which are constrained by the biases of the organism's own immune system and often result in antibodies lacking the desired functionality as a result of being directed to sites on the disease target other than the therapeutically relevant epitope. In addition, as the process is conducted ex vivo, Anaptys can develop antibodies against proteins normally recognized as "self" or that are otherwise known as "difficult" targets, including unstable epitopes, toxins, or even nanotechnology structures.

Boyle continues that unlike static libraries such as antibody phage display libraries that are limited to a finite number of antibody possibilities and might or might not contain an antibody that meets specific design goals, Anaptys' libraries are dynamic and evolved to create antibodies that meet explicit technical specifications. The company also believes that the platform can cut the discovery and optimization time line by half, as well as reduce the resources and costs for the discovery and optimization process.

The platform has potential for both the discovery and optimization of new therapeutic antibodies with medical and commercial potential, as well as for the optimization and maturation of existing antibodies. "Outside therapeutic antibodies, there are additional applications for our technology, such as creating protein-based diagnostic reagents, and industrial enzymes for applications such as biofuels," says Boyle. "Because the platform can evolve more than one protein at a time, we can even create products with synergistic activities," he says.

Anaptys' competitors in the field of antibody generation and modification include Eisai's Morphotek, which is developing antibodies for the treatment of cancer, inflammation, and infectious diseases; **4-Antibody AG**, which is focusing on infectious diseases and severe allergic conditions, including allergic asthma; **EUCODIS GMBH**, which is working in affinity maturation; and **Chiome Bioscience Inc.**, which is also working in affinity maturation, using chicken genetics.

The company's business plan is to build value through its platform, both by using it to create antibodies to partner's targets and affinity mature partner's antibodies, and by developing its own in-house product pipeline. "We expect to generate animal proof-of-concept for our initial product program during the first half of 2008," says Tom Smart. "We have not yet disclosed our targets, but our objective is for the value of the

pipeline to eclipse the value of the platform within the next couple of years." The company will seek partners for its products to maximize their development and commercialization on a worldwide basis. Stage of partnering will be decided on a product basis. "The stage at which we partner will differ—some will be after preclinical studies, some will be once they have entered the clinic, and for a select few, we will keep an eye toward the possibility of taking them all the way to commercialization," says Smart.

Anaptys' key achievements to date have included raising \$3 million in a Series A financing, creating and implementing an industrial version of its platform, beginning development of its in-house pipeline of new antibodies, and generating antibody discovery and affinity maturation data for Series B fund raising and partnering purposes. "We also have great scientific and business leadership behind us," Smart adds, "including the most recent recruit to our board of directors, R. Scott Greer, a founder and former chairman and CEO of Abgenix Inc." Smart himself is the former CBO of antibody company XOMA Ltd., and Boyle led Amgen's first therapeutic antibody program, denosumab.

The company's upcoming financial plans will be to complete a Series B round in the fourth quarter 2007. This will be used primarily to expand the company's operations to support its product development needs and to progress a couple of product candidates into the clinic.

"We face a number of manageable challenges because we are moving into a space that is well validated," Smart says. "We need to make sure that we execute the platform and product programs well and communicate their respective features and advantages clearly. Our objective is to leverage our skill-set and technology to establish long-term importance in the industry." **–Suzanne Elvidge**