

Valneva

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Independently creating global vaccines

With two marketed products, two successful technology platforms and two advanced clinical candidates, Valneva is fast becoming the leading independent vaccine company.

With much of the vaccine industry dominated by big players, niche markets—in which the unmet need for innovative vaccines is often high—tend to be neglected or overlooked. Exploiting this opportunity and leveraging the space between biotech and big pharma is Valneva, a European firm well on its way to becoming *the* leading pure-play and independent vaccine company.

Both a commercial and an R&D enterprise, Valneva offers marketed products, a promising portfolio of R&D candidates and successful technology platforms—a unique business model spanning from discovery and innovation to manufacturing and global commercialization. “No other commercial-stage vaccine biotech company has the same balance between the commercial and R&D side,” said Valneva CEO Thomas Lingelbach.

Valneva currently has two products on the market, both of which are unique travel-related vaccines: IXIARO, designed to protect travelers and military personnel against Japanese encephalitis, the leading cause of viral neurological disease and disability in Asia; and DUKORAL, which is indicated for prevention of cholera and in some countries, diarrhea caused by enterotoxigenic *Escherichia coli* (ETEC), the most severe or frequent cause of travelers’ diarrhea.

The company’s R&D portfolio includes two late-stage clinical products addressing hospital- and health-care-associated infections: lead candidate VLA43, a *Pseudomonas aeruginosa* vaccine (in phase 2/3) to reduce increased mortality associated with hospital-acquired pseudomonas infections in ventilated intensive care unit patients; and VLA84, a vaccine (phase 3 ready) intended to protect against infection by *Clostridium difficile*, the leading cause of health-care-associated diarrhea and an increasing threat to the elderly. Market potential for both vaccines is estimated to be more than \$1 billion per year. Another candidate, VLA15, is a *Lyme borreliosis* vaccine that is about to enter phase 1 and is intended to prevent Lyme disease, the most common vector-borne illness in the northern hemisphere (yearly market potential above €500 million (\$579.2 million)).

Alongside these, Valneva also has two successful, revenue-generating vaccine platforms that have already been widely adopted by the vaccine industry. The first is EB66, a technology based on duck embryonic stem cells for the efficient, large-scale production of a wide variety of viral and therapeutic vaccines. It is a revolutionary alternative to producing vaccines in eggs or chicken embryo fibroblasts. Through agreements with the world’s largest pharmaceutical companies, more than 30 human and veterinary EB66-based vaccines, including GlaxoSmithKline’s future pandemic and seasonal flu vaccines, are currently



being developed utilizing the technology.

The second is IC31, a totally synthetic vaccine adjuvant that can be added to target antigens to improve vaccine response. The potent technology has been licensed to a number of companies and research groups for formulation with new vaccines, including three aimed at preventing tuberculosis, considered as one of the most severe global health problems today.

Created in 2013 through the merger of Vivalis SA and Intercell AG, Valneva today is an independent and fully integrated company focused on vaccines. It is listed on NYSE Euronext and the Vienna Stock Exchange, has a market cap of around €253 million (\$293 million) and, with strong sales growth, is close to operational breakeven.

In 2015, Valneva’s products generated revenues of €83.3 million (\$96.5 million) and are expected to generate almost €100 million (\$115.8 million) in 2016. Furthermore, its fully validated platforms, which have already led to marketed products, generate profits while requiring little investment from Valneva. “Fully developed and with no major costs involved, the technology platforms are nothing but an additional commercial product,” said Lingelbach. “As programs progress, milestones and royalties will significantly increase our financial return, all of which goes to the bottom line.”

In keeping with its long-term strategy of being fully independent, Valneva recently launched its own marketing and distribution network, and now has a commercial presence in the United States, Canada, United Kingdom, Sweden, Norway and Finland (while using leading local distribution partners elsewhere). The network is expected to cover 60% of the company’s total sales this year. “Niche vaccines require specialist marketing, so we’ve taken control of our destiny and are gradually building our own commercial platform,” said Lingelbach. “Valneva now covers the full value chain, from bench to bedside.”

Multiple revenue streams and an international presence have resulted in a financially self-sustainable model that enables Valneva to grow its revenues while also investing at least 20% into its innovative R&D programs, delivering on both patient benefit and market capitalization. “Today our strategic vision is to grow into the single largest pure-play and independent vaccine company,” said Lingelbach. “We are making excellent progress, and our plans to generate organic growth are complemented by opportunistic dealmaking strategies.”

Partnering

Through partnerships with the world’s leading pharmaceutical and biotech companies, Valneva has established a successful track record in out-licensing its programs and technologies—a strategy it hopes to continue.

Valneva’s proprietary EB66 and IC31 platforms are available for research and commercial licensing. “We have one of the best-developed platforms to manufacture viral vaccines and adjuvants with a unique proposition in proven indications,” said Lingelbach. “As a technology provider we are very open to new routes of partnering these in novel indications, territories or disease areas.”

In its discovery research, Valneva pursues ‘open innovation’—a modern way to add value through partnerships with academia and the newest state-of-the-art industrial knowledge.

Additionally, Valneva is actively seeking not only licensing partners for advanced candidates such as its *C. difficile* vaccine but also new partners to develop or codevelop selected programs from its earlier-stage R&D pipeline portfolio.

Leveraging its newly built commercial presence, Valneva is now keen to acquire additional commercial vaccine assets from or add value to a third party seeking distribution of vaccine products.

“We are looking for partners in all areas—from research to commercialization—that would allow us to share opportunities and mutual commercial benefits and support our mission to advance vaccines for better lives,” Lingelbach said.

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