

Drug Delivery Technology: Developing a New Generation of Vaccines

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Abstracts

Use the incisive analysis, commentary, opinions and forecasts provided in this note to:

gain an in-depth understanding of the technology landscape for vaccines and vaccine delivery technologies including immune potentiators, adjuvant delivery systems, delivery of DNA vaccines, delivery to the mucosal system and skin, needle-free delivery and single shot vaccines

assess the options available for delivering DNA vaccines now & in the future

assess the potential of mucosal delivery options for emerging products

gauge the current & future technology requirements of manufacturers developing the new generation of vaccines

analyze how the market is evolving & the influence that delivery may have on the development of prophylactic vaccines for complex and emerging infectious diseases, biodefense vaccines and therapeutic vaccines

identify key pharma & delivery specialists focusing on the improved delivery of prophylactic and therapeutic vaccines

KEY FINDINGS:

The 2006 global vaccines market is worth around US\$9billion.



This market has attracted attention of specialty pharma and is of increasing interest to big pharma. The major players in the field are GlaxoSmithKline, Novartis, MedImmune (acquired by AstraZeneca), Merck & Co, sanofi-aventis and Wyeth.

Challenges remain to ensure the safe and efficient manufacture and delivery of vaccines and the promotion of a sufficient humoral and cellular response to provide long-term immunity.

Forecasts for near-term (2006-2012) and future (2020) market growth based on the technology platforms evaluated in the report.

Plus, sales forecasts for approved and pipeline vaccines and adjuvants.

Many new vaccines (bacterial, protein, DNA and viral based vaccines) will reach the market over the next 6 years, driving future market growth. Their success is analyzed in detail and case studies are provided to highlight the progress of each technology.

Researchers are increasingly using rational drug development techniques to identify immune potentiators that stimulate specific parts of the immune system resulting in a cellular, humoral and/or mucosal immune response. A number of these agents currently in clinical trials are evaluated in this report.

Specialists are exploring alternative delivery routes including intranasal, oral, transdermal as well as needle-free injectors and micro-needles for parenteral delivery.

As our understanding of immunobiology grows and the vaccine market evolves, companies are adopting new approaches in vaccines for emerging diseases and therapeutic vaccines. Pharmaceutical companies continue to license and acquire the necessary skills in order to expand their product portfolio and capitalize on this innovative and expanding marketplace. Market trends, recent alliances and acquisitions are analyzed in detail in the report.

Introduction



"Over the past year, excitement within the industry has been growing as companies start to recognize the potential of vaccines. New i nsights into immunobiology and delivery systems may allow the development of better vaccines and vaccines for a wider range of diseases than was previously possible. The market looks set to explode over the next 5-10 years as a raft of new products based on these new technologies are developed and launched."

Dr Sara Sleigh

Vaccination is recognized as a cost-effective medical strategy. Vaccines, alongside antibiotics and improved hygiene standards, have been responsible for a steady decrease in morbidity and mortality from infectious diseases worldwide since their introduction early in the 20th century. Currently available vaccines prevent up to 3 million deaths each year and 750,000 children avoid serious disability. Despite this high level of success, almost 7 million children under 5 years old still die each year from infections.

Conventional vaccines have been based on live attenuated, or killed, viruses or bacteria, or recombinant proteins from these organisms. The design of live attenuated vaccines depended to some extent on serendipity and resulted in low success rates; both live attenuated and killed vaccines require handling live pathogens and are associated with safety problems. Vaccines based on recombinant protein antigens are not highly immunogenic, proteins can be difficult to manufacture and may have stability issues.

Recent scientific advances have increased our understanding of immunobiology and now allow the more rational design of vaccines. These advances include new delivery technologies that will improve the safety and immunogenicity of traditional vaccines as well as introducing entirely new methods of vaccine delivery such as DNA vaccines. It is largely through the development of new delivery methods that companies are now aiming to tackle infectious diseases that have evaded vaccine manufacture in the past, develop vaccines for potential diseases related to bioterrorism and launch the new category of therapeutic vaccines.

Vaccines are a vibrant area of pharmaceutical development. The activity in the marketplace has grown steadily over the past few years and looks set to continue and increase in the near future. This report describes the role of new delivery technologies in this rapidly growing field.



EIGHT QUESTIONS THIS NOTE ANSWERS:

- 1. How will the delivery technology drivers change in the vaccine arena during the next decade and beyond?
- 2. What are the key delivery technologies and devices approved and under development in the vaccines market?
- 3. When are products and devices which utilize these key delivery technologies likely to reach the market?
- 4. Which delivery technologies and agents are likely to win in the near-term and the long-term, and why?
- 5. Which companies are the winners in each technology category?
- 6. How are delivery technologies evolving to meet the demands of vaccine manufacturers who are now targeting emerging diseases, biodefense and therapeutic vaccines?
- 7. Where are the market opportunities now and in the future?
- 8. What do we predict will be the value of the vaccines delivery market each year until 2012, in 2015 and in 2020?



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COMPANIES MENTIONED:

Acambis, ACE Biosciences, Allergy Therapeutics, Alba Therapeutics, Alphavax, Altea Therapeutics, AnGes MG, Antares Pharma, Antigenics, Corixa (acquired by GlaxoSmithKline), Avant Immunotherapeutic, Bavarian Nordic, Baxter Healthcare, Bayhill Therapeutics, Becton Dickinson, Berna Biotech, Bharat Biotech International Limited, Biomira (shortly to change its name to Oncothyreon), Bioject Medical Technologies Inc, BioVex, BN Immunotherapeutics Inc, Brookwood Pharmaceuticals, Cambridge Biostability, Celldex Therapeutics Inc, Cerus Corporation, Coley Pharmaceuticals (acquired by Pfizer), CrossJect Medical Technology, Crucell, CSL Ltd, Cure Vac, Cytos Biotechnology, CytoPulse Sciences Inc, DelSite, Dynavax Technologies, DynPort Vaccine Company, Eli Lilly, Eiffel Technologies, Eisai, Emergent Biosolutions, EPFL, Eurocine Vaccines, GeneVac, GlaxoSmithKline, Genexine, Glide Pharma, Globelmmune, GeoVax, chor Medical Systems, ID Biomedical Corporation, Idera Pharmaceuticals, Iomai Corporation, mmutep, Intercell, Introgen Therapeutics, InovivoGen, Inovio, Injex, LigoCyte Pharmaceuticals, MedImmune (acquired by AstraZeneca), Merck & Co, Merck KGaA, Midatech Group, NanoBio, Nanomed Pharmaceuticals, NanoPass Technologies, NanoVic, NasVax, Nventa (formerly Stressgen Biotechnologies), Novartis, Novavax, OctoPlus, OM Pharmceuticals, Oxford BioMedica, Panacea Biotech, PenJet Corporation, Pevion Biotech, Pfizer, Pharmexa, PowderMed (previously part of Chiron Corporation, acquired by Pfizer), pSivida, Roche, Sanofi Pasteur, sanofi-aventis, Targeted Genetics, Therion Biologics, Transgene, Valeritas, VaxInnate, Vaxiion Therapeutics, Vaxin Inc, VGX Pharmaceuticals, Vical Inc, Virxsys, Wyeth, Zogenix, 3M Pharmaceuticals.



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