

****New release April 2014****

MarketVIEW: Lyme Borreliosis vaccines (CAT: VAMV024)

Product Name	:	MarketVIEW: Lyme Borreliosis (LB) vaccines
Description	:	Global vaccine commercial opportunity assessment
Contents	:	Executive presentation + forecast model
Therapeutic Area	:	Novel vaccines
Publication date	:	April 2014
Catalogue No	:	VAMV024

Background

Lyme Borreliosis (LB) or Lyme disease is caused by an infection with the bacterial spirochete *Borrelia* genospecies. The pathogen is transmitted to humans through the bite of infected *Ixodes* tick species. LB, which is endemic in large areas of Europe and North America, can cause a wide range of disease symptoms which range from a mild treatable rash to serious complications of the neurological system (neuroborreliosis). The incidence of LB in the US has tripled in the last 15 years and is also significant in continental Europe. GSK Biologicals licensed a recombinant vaccine (LYMErix) in 1998 which was later withdrawn due to a number of reasons.

This **MarketVIEW** product is a comprehensive MS Excel-based model + summary presentation which forecasts the potential commercial value of new Lyme Borreliosis vaccines across endemic markets to 2035. The model contains value (\$ m) and volume (mio doses) predictions for each country and discusses current dynamics in disease incidence with comprehensive epidemiological reviews and risk maps. The analysis also covers a GSK LYMErix case study, cost effectiveness and new LB vaccine target product profiles e.g. Baxter Vaccines. It is essential reading for any organisation wishing to reconsider the development of new LB vaccines.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to Lyme Borreliosis epidemiology/vaccines. Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by **VacZine Analytics** in field of endemic vaccines has also been utilised.

PRODUCT CONTENTS:

Published April 2014 (CAT No: VAMV024)

****This product is composed of a model and summary presentation

Contents – Summary presentation (MS PowerPoint based)

Author's note
Executive Summary
Lyme Borreliosis vaccines: available market EU+US (\$ 000s) to 2035
Lyme Borreliosis vaccines: available market per country (\$ 000s) to 2035
Lyme Borreliosis vaccines: predicted demand EU+US (Doses 000s) to 2035
Lyme Borreliosis vaccines: predicted revenues per competitor to 2035
Lyme Borreliosis: disease background
Lyme Borreliosis: latest disease trends and dynamics
Lyme Borreliosis: background
Lyme borreliosis: vector lifecycle and distribution
Global vector distribution
Ixodes ricinus distribution, Europe, March 2013
Genospecies distribution
Distribution of Borrelia genospecies in Europe
Clinical features
Clinical features of confirmed LB cases, US, 2001-10
Comparison of clinical features of LB, US and Europe.
Diagnosis and treatment
Age, sex and racial distribution
Confirmed LB cases by age and sex, US, 2001-2010
Epidemiology – US
Confirmed and probable LB cases, US, 2003-2012
Confirmed cases of LB, US, 2001 and 2012
LB incidence rate by state, confirmed cases, 2012.
Focus on southern New Hampshire, 2012
Epidemiology – EU
Annual number of LB cases per country, Europe
Lyme borreliosis: vaccine history and development
Vaccines: competitive landscape
Lyme Borreliosis vaccines: target product profiles
Baxter's LB vaccine
Baxter's LB vaccine: frequency of local and systemic reactions
Lyme Borreliosis vaccines: GSK's LYMERix
Negative public perception of LYMERix
Challenges to gaining US market acceptance
Cost-effectiveness of Lyme disease vaccination
Lyme borreliosis: modelling commercial potential
Methodology

Countries/regions included in the model
Major commercial model assumptions
Commercial model assumptions by country
Appendix I – Lyme borreliosis: focused country overview
Austria
Belgium
Croatia
Czech Republic
Estonia
Finland
France
Germany
Hungary
Italy
Latvia
Lithuania
The Netherlands
Norway
Poland
Slovakia
Slovenia
Sweden
Switzerland
Other countries
Appendix II – Lyme borreliosis: country risk maps
US risk areas
Belgium risk areas
Croatia risk areas
France risk areas
Germany risk areas
Hungary risk areas
Finland risk areas
Bibliography
About VacZine Analytics
Disclaimer

PAGES: 105 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form

Contents – Vaccine demand model (MS Excel-based)

Title sheet
Total charts
Charts value
Charts volume
Value summary (TOTAL MARKET)
Volume summary (TOTAL MARKET)
US (base) adult
US (base) infant
Austria (base) adult
Austria (base) infant
Belgium (base) adult
Belgium (base) infant
Croatia (base) adult
Croatia (base) infant
Czech (base) adult
Czech (base) infant



Estonia (base) adult
Estonia (base) infant
Finland (base) adult
Finland (base) infant
France (base) adult
France (base) infant
Germany (base) adult
Germany (base) infant
Hungary (base) adult
Hungary (base) infant
Lithuania (base) adult
Lithuania (base) infant
Latvia (base) adult
Latvia (base) infant
Holland (base) adult
Holland (base) infant
Poland (base) adult
Poland (base) infant
Slovakia (base) adult
Slovakia (base) infant
Slovenia (base) adult
Slovenia (base) infant
Sweden (base) adult
Sweden (base) infant
Switzerland (base) adult
Switzerland (base) infant
Source material
Incidence rates (US)
Incidence rates (EU)
Populations at risk
Genospecies

WORKSHEETS: ~56

PRODUCT COST:

VacZine Analytics will grant a [enter region] license to [enter client name], for the price of:

- USD \$8995.00/ GBP £5620.00[#] (Region license)*

*A region is North America, Europe or ROW

For orders in the UK, VAT at 20% will be added to final invoice total

- indicative prevailing rate will be applied on date of transaction

HOW TO ORDER:

To order please contact your region account manager or order direct at orders@vaczine-analytics.com

This report can also be purchased on-line. Please review the **TERMS and CONDITIONS** of purchase.



VacZine Analytics (R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

VacZine Analytics (R) and the “spiral logo” are UK Registered Trademarks, 2009

BIBLIOGRAPHY:

1. Stanek G et al. Lyme Borreliosis. Lancet 2012; 379: 461-73
2. Meyerhoff JO. Lyme disease. Emedicine May 2013. Available at: <http://emedicine.medscape.com/article/330178-overview>. Accessed March 2014
3. CDC. Lyme disease transmission. Available at: <http://www.cdc.gov/lyme/transmission/index.html>. Accessed March 2014
4. ECDC. Tick species-distribution maps. Available at: <http://www.ecdc.europa.eu/en/healthtopics/vectors/vector-maps/Pages/VBORNET-maps-tick-species.aspx>. Accessed March 2014
5. ECDC. Lyme Disease. Factsheet for health professionals. Available at: <http://www.ecdc.europa.eu/>. Accessed: March 2014
6. Rauter C et al. Prevalence of Borrelia burgdorferi sensu lato genospecies in Ixodes ricinus ticks in Europe: a metaanalysis. Appl Environ Microbiol. 2005 Nov;71(11):7203-16.
7. Fingerle V et al. Epidemiological aspects and molecular characterization of Borrelia burgdorferi s.l. from southern Germany with special respect to the new species Borrelia spielmanii sp. nov. Int J Med Microbiol. 2008 Apr;298(3-4):279-90.
8. Maraspin V et al Lyme borreliosis and Borrelia spielmanii. Emerg Infect Dis. 2006 Jul;12(7):117
9. Clark KL et al. Geographic and genospecies distribution of Borrelia burgdorferi sensu lato DNA detected in humans in the United States. J Med Microbiol. 2014 Feb 25.
10. CDC. Signs and Symptoms of Lyme Disease. Available at: http://www.cdc.gov/lyme/signs_symptoms/index.html. Accessed: March 2014
11. CDC. Clinical Manifestations of Confirmed Lyme Disease Cases--United States, 2001-2010. Available at: <http://www.cdc.gov/lyme/stats/chartstables/casesbysymptom.html>. Accessed: March 2014
12. Lyme-Borreliose: Analyse der gemeldeten Erkrankungsfälle der Jahre 2007 bis 2009 aus den sechs östlichen Bundesländern. Epidemiologisches Bulletin 12/2010.
13. Lyme-Borreliose: Sentinella-Erhebung 2008/2009 - Das Nationale Referenzzentrum für Zecken und zeckenübertragene Krankheiten stellt sich vor. Bull BAG 2010; Nr. 22: 579-582. 31.05.2010.
14. Stanek G et al. Lyme borreliosis: clinical case definitions for diagnosis and management in Europe. Clin Microbiol Infect. 2011 Jan;17(1):69-79.
15. CDC. Confirmed Lyme disease cases by age and sex--United States, 2001-2010. Available at: <http://www.cdc.gov/lyme/stats/chartstables/incidencebyagesex.html>. Accessed: March 2014
16. CDC. CDC provides estimate of Americans diagnosed with Lyme disease each year. Available at: <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html>. Accessed: March 2014
17. CDC. Lyme Disease Incidence Rates by State, 2003-2012. Available at: <http://www.cdc.gov/lyme/stats/chartstables/incidencebystate.html>. Accessed: March 2014
18. Reported Cases of Lyme Disease by Year, United States, 2003-2012. Available at: <http://www.cdc.gov/lyme/stats/chartstables/casesbyyear.html>. Accessed: March 2014
19. US CDC. Reported Cases of Lyme Disease Map, United States, 2012. Available at: <http://www.cdc.gov/lyme/stats/maps/map2012.html> Accessed: November 2013
20. New Hampshire Department of Health and Human Services. Available at: <http://www.dhhs.nh.gov/dphs/cdcs/lyme/publications.htm>. Accessed: March 2014
21. ECDC Meeting Report. Second expert consultation on tickborne diseases with an emphasis on Lyme borreliosis and tickborne encephalitis. November 2011. Available at: <http://www.ecdc.europa.eu/en/publications/Publications/Tick-borne-diseases-meeting-report.pdf>. Accessed March 2014.
22. Lindgren and Jaenson, 2006, Lyme borreliosis in Europe: influences of climate and climate change, epidemiology, ecology and adaptation measures, WHO Regional Office for Europe, ISBN: 9289022914
23. ECDC issues call for tenders on Lyme borreliosis. May 21st 2013. Available at: <http://www.edenext.eu/the-project/news/ecdc-issues-call-for-tenders-on-lyme-borreliosis> . Accessed: November 2013.
24. Huff Post Impact. The Global Search for Education: Germany – Ticks. Available at: http://www.huffingtonpost.com/c-m-rubin/the-global-search-for-edu_b_3839801.html. Accessed March 2014.
25. Wressnigg N. et al. Safety and immunogenicity of a novel multivalent OspA vaccine against Lyme borreliosis in healthy adults: a double-blind, randomised, dose-escalation phase 1/2 trial. Lancet Infect Dis. 2013 Aug;13(8):680-9.
26. Claudia Rowe. Lukewarm Response To New Lyme Vaccine. June 13, 1999. Available at: <http://query.nytimes.com/gst/fullpage.html?res=9C05E4D71238F930A25755C0A96F958260>. Accessed: March 2014
27. Lyme disease. Vaccine Production. Background. Available at: <http://www.niaid.nih.gov/topics/lymedisease/research/pages/vaccine.aspx>. Accessed: March 2014
28. LymeRix Vaccine Victim's Stories. Available at: www.fda.gov/OHRMS/DOCKETS/ac/01/briefing/3680b2_17.pdf. Accessed: March 2014

29. Aronowitz RA. The rise and fall of the lyme disease vaccines: a cautionary tale for risk interventions in American medicine and public health. *Milbank Q.* 2012 Jun;90(2):250-77.
30. VacZine Analytics. MarketVIEW – Tick-borne Encephalitis (CAT No: VAMV022), published October 2010
31. Stanek G. The epidemiology of Lyme disease in Austria Update 2008. Available at: www.antibiotikamonitor.at/08_23/08_23_01.htm. Accessed: March 2014.
32. Epidemiologie en aanpak van de ziekte van Lyme in de huisartsenpraktijken in België. Available at: <http://www.infectieziektebulletin.be/defaultSubsite.aspx?id=9432>. Accessed: November 2010.
33. Vanthomme K et al. Incidence and management of presumption of Lyme borreliosis in Belgium: recent data from the sentinel network of general practitioners. *Eur J Clin Microbiol Infect Dis.* 2012 Sep;31(9):2385-90
34. Mulić R et al. Epidemiological characteristics and clinical manifestations of Lyme borreliosis in Croatia. *Mil Med.* 2006 Nov;171(11):1105-9
35. Lymeská borrelióza - epidemiologická data. Available at: <http://www.szu.cz/tema/prevence/lymeska-borrelioz-a-epidemiologicka-data-1>. Accessed November 2010
36. Infections in the Czech Republic in 2013, cumulative. Available at: <http://www.szu.cz/publikace/data/kumulativni-nemocnost-vybranych-hlasenych-infekci-v-ceske>. Accessed November 2013
37. Bochníčková M et al (2013) Lyme Disease in Northern Slovakia (1989-2010): Clinical and Epidemiological Characteristics. *Epidemiol* 3: 125.
38. Bazovska S et al. Reported incidents of Lyme disease and Slovakia and antibodies to *B.burgdorferi* antigens detected in healthy population. *Bratisl Lek Listy* 2005; 106 (8-9) 270-273
39. Estonia, the tick-borne Lyme disease rages. *Encyclopedia of safety.* Available at: <http://survincity.com/2012/01/in-estonia-the-tick-borne-lyme-disease-rages/>. Accessed March 2014
40. Tick-Borne Illness Increase Highest in West, on Islands. Estonian public broadcasting. Published 20th January 2012
41. Finland. Infectious Diseases Register. Available at: <http://www3.thl.fi/stat/> Accessed: November 2013
42. TOUCHED BY LYME: Tick-borne illnesses in Finland. Lyme disease.org .Available at: http://lymedisease.org/news/lyme_disease_views/ticks-finland.html. Accessed: November 2013
43. La maladie de Lyme. Données du réseau de surveillance de la maladie en Alsace Mars 2001 - Février 2003 Institut de veille sanitaire
44. Surveillance de la maladie de Lyme Région Limousin Bulletin d'information n°2. Période de surveillance du 1er avril 2004 au 31 mars 2006
45. Surveillance de la maladie de Lyme - Département de l'Ain, de la Loire et de la Haute-Savoie
46. Beytout J et al. Lyme borreliosis incidence in two French departments: correlation with infection of Ixodes ricinus ticks by *Borrelia burgdorferi* sensu lato. *Vector Borne Zoonotic Dis.* 2007 Winter;7(4):507-17.
47. Inserm (Sentinelles) Available at: <http://websenti.b3e.jussieu.fr/sentiweb>. Accessed November 2013
48. Robert Koch Institute. Epidemiologisches Bulletin. Seroprävalenz der Lyme-Borreliose bei Kindern und Jugendlichen in Deutschland. 10. April 2012 / Nr. 14.
49. German Federal Health Monitoring. Available at: <http://www.gbe-bund.de>. Accessed: March 2014
50. Információk a kullancsok által terjesztett betegségekéről 2007. július 18. Available at: <http://www.eum.hu>. Accessed: November 2010
51. Bozsik BP et al. Prevalence of Lyme borreliosis. *The Lancet*, Volume 363, Issue 9412, Page 901, 13 March 2004
52. Zoldi. V et al. Tick-borne encephalitis and lyme disease in Hungary: the epidemiological situation between 1998 and 2008. *Vector Borne Zoonotic Dis.* 2013 Apr;13(4):256-65
53. Malattia di Lyme. *Epidemiologia.* Available at: <http://www.antropozoonosi.it/Malattie/Malattia%20di%20Lyme/ispesi%20LYME/epidemiologiag.htm> Accessed: November 2010.
54. Ricoveri, diagnosi, interventi effettuati e durata delle degenze di tutti gli ospedali. Available at: http://www.salute.gov.it/ricoveriOspedali/ric_informazioni/default.jsp. Accessed: November 2010.
55. Pascucci I et al. Lyme disease and the detection of *Borrelia burgdorferi* genospecies in Ixodes ricinus ticks from central Italy. *Veterinaria Italiana*, 46 (2) 181-188
56. Bormane A., I. Lucenko, A. Duks, V. Mavtchoutko, R. Ranka, K. Salmiņa, and V. Baumanis. 2003. Vectors of tick-borne diseases and epidemiological situation in Latvia in 1993-2002. *IntJMedMicrobiol.* 293, Suppl. 37, 36-47.
57. M. Žygutienė. Tick-Borne Pathogens and Spread of Ixodes ricinus in Lithuania. *EpiNorth.*2009;10(2):63-71.
58. M. Žygutienė. Tick-Borne Pathogens and Spread of Ixodes ricinus in Lithuania. *EpiNorth.*2009;10(2):63-71.
59. Hofhuis A et al. Ziekte van Lyme in Nederland 1994-2009. Aantal huisartsenconsulten blijft toenemen; is voorlichting en curatief beleid alleen genoeg? *Utrecht: Infectieziekten Bulletin*, April 2010. Nummer 3. Available at: http://www.rivm.nl/cib/publicaties/bulletin/jaargang_21/bull_2103/ziekte-van-lyme-in-nederland-1994-2009.jsp. Accessed: November 2010.
60. Coumou J et al. Tired of Lyme borreliosis. *Lyme borreliosis in the Netherlands.* *Neth J Med.* 2011 Mar;69(3):101-11.

61. Deuning CM (RIVM). Erythema migrans, 2009. In: Public Health Status Survey, National Atlas of Public Health. Bilthoven: RIVM, Atlas. Available at: <http://www.zorgatlas.nl>. Accessed: November 2010.
62. Folkehelseinstitutt. MSIS Statistic. Available: <http://www.msis.no/>. Accessed November 2013
63. Rubin CM. The Global Search for Education: Norway – Ticks. Available at: http://www.huffingtonpost.com/c-m-rubin/the-global-search-for-edu_b_3777332.html. Accessed November 2013
64. Norwegian Institute of Public health. Lyme disease. Available: <http://www.fhi.no>. Accessed November 2013
65. Przegl Epidemiol 2001 ;55 Suppl 3:187-94.
66. Berger SA. Lyme disease: Global Status, 2010, 66 pp. Gideon e-book series.
67. Lewandowska A et al. Epidemiology of Lyme disease among workers of forest inspectorates in Poland. Annals of Agricultural and Environmental Medicine 2013, Vol 20, No 2, 329–331
68. Strle F et al. Clinical manifestations and diagnosis of lyme borreliosis. Curr Probl Dermatol. 2009;37:51-110.
69. Institute of Public Health . Sezona klopotov se je pričela. May 2006. Available at: <http://www.ivz.si/>. Accessed: November 2010
70. Inštitut za varovanje zdravja RS (IVZ). Health statistical Yearbook 2011. Available at: <http://www.ivz.si/>. Accessed: November 2013
71. Wallensten A. Large discrepancy between the current estimate of Swedish Lyme borreliosis incidence and the number of diagnoses made in primary care. ESCAIDE 2010
72. Altpeter E et al. Tick related diseases in Switzerland, 2008 to 2011. Swiss Med Wkly. 2013;143:w13725
73. Epidemiology of Lyme borreliosis in the UK. Available at: <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/LymeDisease/EpidemiologicalData/lymLymeepidemiology> Accessed: November 2013.
74. Ogden NH, et al. The emergence of Lyme disease in Canada. CMAJ. 2009 Jun 9;180(12):1221-4
75. Dessau RB et al. Utilization of serology for the diagnosis of suspected Lyme borreliosis in Denmark: Survey of patients seen in general practice. BMC Infect Dis. 2010 Nov 1;10(1):317.

TERMS and CONDITIONS:

VacZine Analytics – a trading division of Assay Advantage Ltd UK Company Number: 5807728 (Herein referred to as “The Company”). (Herein [enter client name] to as “The Client”).

1. This finished research product is provided is provided as a Service. Any additional Service required by the client will be subject to a new proposal being prepared.
2. The Service will commence after written (e-mail) or Fax confirmation stating the Client's acceptance of the Service according the description proposed by the Company.
3. **Cancellation policy.** The Company's cancellation policies are in accordance with the EU Consumer Protection (Distance Selling) Regulations 2000 (DSRs). Prior to acceptance of an order the Company will make available written information regarding Clients cancellation rights. This is posted on the Company website and is available for public review.
4. **Cancellation rights:** For finished documents - a Clients cancellation rights will last for **seven working days** counting from the day that the order was concluded. If the Services i.e. provision of the documents has taken place with the Clients agreement before this period the Client's cancellation rights have ended.
5. Invoicing will **100%** after submission of deliverables to the Client in a form reasonably acceptable to the Client.
6. If not purchased on line invoices are payable within **thirty days** of the invoice date.
7. All proposals are quoted in **\$USD dollars or £GBP** and invoices are to be settled in the same currency.
8. The Company agrees not to disclose to any third party confidential information acquired in the course of providing the services listed without the prior written consent of the Client. Exception occurs when the information is already in the public domain or when disclosure is necessary to help the Company's employees and agents with the performance of the Company's obligations to achieve satisfactory completion of the project and approved in writing by the Client.
9. Force Majeure: The Company will not be liable for any delay or failure to perform any obligation under this Agreement insofar as the performance of such obligation is prevented by an event beyond our reasonable control, included by not limited to, earthquake, fire, flood or any other natural disaster, labour dispute, riot, revolution, terrorism, acts of restraint of government or regulatory authorities, failure of computer equipment and failure or delay of sources from which data is obtained.
10. Please also refer to Master **TERMS and CONDITIONS** available upon request.

VacZine Analytics

Warren House
Bells Hill
Bishops Stortford
Herts
CM23 2NN
United Kingdom
Tel: +44 (0) 1279 654514 / +44 (0) 7952470582 / Fax: +44 (0) 1279 655926
E-mail: info@vacZine-analytics.com

About VacZine Analytics:

VacZine Analytics is an established strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics.

For more information please visit our website www.vacZine-analytics.com

VacZine Analytics (R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

VacZine Analytics (R) and “the spiral logo” are UK Registered Trademarks, 2009