Advancing vaccines for better lives

Company presentation
January 2020

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Valneva's value proposition

Integrated business model with valuable commercial and R&D assets

Commercial Business

Total sales revenues €125m - €130m[1]

IXIARO®
- Only licensed JE-Vaccine for travelers, Military in North America, CAN, EU
- Sales approaching €100m[1]

DUKORAL®
- Cholera (LT-ETEC) Vaccine, licensed in CAN, EU, ROW
- Sales > €30m[1]

Recent transactions underline major valuation disconnect
BN product acquisition from GSK @ 4.5x revenue

R&D

Lyme vaccine in Phase 2 with data reading out from mid-2020

US/EU market opportunity of ~$1bn per annum
- Only program in clinical development
- Commercial/development partner tbc

Chikungunya vaccine entering Phase 3 in Q2 2020

Global market opportunity of ~$0.5bn per annum
- Huge synergy with existing infrastructure
- Possible Priority Review Voucher upside

R&D provides upside for shareholders
Two unique vaccines with low R&D risk profile to be launched in the next 3-4 years

1 Based on company 2019 guidance

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet medical needs

€125m–€130m product sales
~ 80% direct sales
~ 70% in North America

~ €65m cash
Planning further debt facility to support growth pre US IPO

~ 65% gross margin
~ €40m EBIT[1]

~500 people
Four main sites
Six in-market commercial teams

1 Estimated commercial business EBIT excluding R&D, **2** 2019 Company guidance

Lyme Disease Vaccine – VLA15

Overview of Lyme disease

The fastest growing and most feared tick-borne illness in the Northern Hemisphere

~300,000

Annual cases in the U.S.[1]

~200,000

Annual cases in the EU[1]

x3

Reported cases have tripled in the U.S. over 20 years[1]

Unmet Need

- There are no approved options that can protect humans against Lyme disease
- Tick avoidance measures are often ineffective

Market Opportunity

- Analysis suggests a Lyme vaccine in the US and EU could have peak revenue potential of more than ~$1b[1]
- Many high-profile sufferers including Justin Bieber

1 Lyme Disease. L.E.K. interviews, research and analysis

VLA15

The only Lyme disease vaccine candidate in clinical development today

1. Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe
2. Phase 2 interim data (primary endpoint) expected mid-2020
3. FDA Fast Track Designation granted
4. Established and proven Mode of Action for a Lyme disease vaccine
5. Favorable safety profile and no associated safety concerns in Phase 1 studies[1]
   Phase 2 run-in (higher dosages than Phase 1) confirmed favorable safety profile of VLA15

1 Valneva PR: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate

VLA15: Phase 2 – Optimizing dose and schedule

Observer-blind, randomized, placebo-controlled, Phase 2 studies conducted in the US and EU[1]

Phase 2
819 subjects in two studies
Primary objective: Safety and immunogenicity data four weeks after completed schedule
Secondary objectives: Long-term immunogenicity and safety data

Study **VLA15-201** with run-in phase

Study **VLA15-202**

Enrollment completed for both studies

VLA15-201 Run-in phase (completed June 2019[2])

- Conventional schedule, higher dose
- **3 adjuvanted dose levels, placebo**
- **120 healthy volunteers** (18 to 40 years)

90 µg w/ alum	30 subjects
135 µg w/ alum	30 subjects
180 µg w/ alum	30 subjects
Placebo	30 subjects

VLA15-201 (initiated June 2019[2]): Schedule 0, 1, 2 months

- **2 adjuvanted dose levels** (135 µg and 180 µg) chosen after run-in phase, placebo
- **453 healthy volunteers** (18 to 65 years)
- **9 sites in the U.S. and Europe**

VLA15-202 (initiated July 2019[3]): Schedule 0, 2, 6 months

- **2 adjuvanted dose levels** (135 µg and 180 µg) chosen after run-in phase, placebo
- **246 healthy volunteers** (18 to 65 years)
- **5 sites in the U.S.**

1 VLA15-201 only (ClinicalTrials.gov Identifier: NCT03769194); Phase 2 subjects are baseline seropositive (10%) or seronegative (90%); **2** Valneva PR: Valneva Reports Successful Outcome of Phase 2 Run-In for its Lyme Disease Vaccine Candidate; **3** Valneva PR: Valneva Initiates Second Phase 2 Study for its Lyme Disease Vaccine Candidate VLA15 ; VLA15-202 ClinicalTrials.gov Identifier: NCT03970733

VLA15 Phase 2 on track

Status and clinical development overview

Patient recruitment for both Phase 2 studies completed September 2019

Partnering process (for late stage development & commercialization) initiated

Phase 2 first data due mid-2020

- Initial data: Day 85 after base immunization schedule expected mid-2020

Phase 3 planned during 2021/2022

- Two placebo-controlled Phase 3 efficacy studies
  - 8,000 subjects in each of US and Europe
  - Based on current estimates of Lyme incidence rates in order to demonstrate efficacy of the vaccine in Lyme endemic regions in the U.S. and Europe
- Detailed plans for Phase 3 entry to be discussed with FDA based on Phase 2 data
- Timing depends on schedule, tick season(s), Ph2 data and other factors

*Subject to development progress, regulatory approvals and company funding

Chikungunya Vaccine – VLA1553

Overview of chikungunya disease

A highly prevalent mosquito-borne infection in tropical and subtropical regions

>1,100

Cases reported in EU[1] as of 2018

>460

Traveler cases reported in the U.S., with the highest number of cases reported in NY and FL[1]

~45% of overseas U.S. troops are deployed in regions with high and medium risk of chikungunya transmission[2]

In Brazil alone, over 350,000 probable cases were reported between 2013 and 2015

Unmet Need

- There are currently no treatment options for chikungunya
- Current treatments focus on symptom relief through use of analgesics

Market Opportunity

- Global market potential of up to $500m
- Valneva's chikungunya vaccine potential is estimated at > €200m[1]

1 Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market. 2 DMDC; L.E.K. research and analysis

VLA1553

The only single-shot vaccine candidate against chikungunya today

1. VLA1553 is a monovalent live attenuated[1] prophylactic vaccine targeting chikungunya virus neutralization
2. Currently no preventive vaccines or effective antiviral treatments exist for chikungunya
3. FDA Fast Track Designation granted. Priority Review Voucher eligible
4. Phase 1 complete. Aiming for accelerated approval pathway with potential Phase 3 start in Q2 2020; FDA EoP2 meeting February 2020
5. Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset
6. Up to $23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI

1 CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; Photo credit: James Gathany (source)

Chikungunya Phase 1 study (VLA1553-101) – Final results

Sustained immunogenicity with single shot for over one year

Immunogenicity

100% Seroconversion Rate (SCR)[1] achieved at Day 14 after a single vaccination in all dose groups[2]

SCR sustained at 100% after 13 months with no decline in neutralizing antibody titers in the groups after a single vaccination[2]

Excellent immunogenicity profile after single vaccination

Safety[2]

Generally safe in all dose groups

Well-tolerated at the low and medium doses

- Superior safety profile, including viremia, in low and medium doses compared to highest dose

Excellent local tolerability

No adverse events of special interest (e.g. chikungunya infection related) and no vaccine related Serious Adverse Events (SAEs) up to Month 13

Excellent safety profile in low and medium doses[2]

1 SCR defined as proportion of subjects achieving a CHIKV-specific neutralizing antibody titre as $NT_{50} \geq 20$; **2** Valneva Reports Excellent Final Phase 1 Results for its Chikungunya Vaccine Candidate, Confirms Plans

VLA1553 progressing rapidly

Status and clinical development overview

End of Phase 2 (EoP2) FDA meeting scheduled for February 2020

- Potential for Phase 3 to begin in Q2 2020

Additional non-clinical studies to support EoP2 FDA meeting fully completed

- Mosquito transmission studies
- NHP study addressing biodistribution
- Passive transfer study in NHPs to develop surrogate of protection using human sera from VLA1553-101

Aiming for accelerated approval pathway to move directly into Phase 3*

*Subject to FDA approval

VLA1553 is expected to be highly differentiated

Competition overview

	Valneva	Emergent (Paxvax)	Themis
Vaccine candidate	Monovalent, single dose, live-attenuated vaccine candidate	Virus-like particle (VLP) vaccine	Measles-vectored Chikungunya vaccine (MV-CHIK), Live-recombinant vaccine
Schedule	Single-shot - Day 0	2 shots - Day 0 & 28	2 shots - Day 0 & 28
Development stage	Phase 1 in U.S. complete (manuscript in preparation) No Phase 2 trial needed (single shot efficacy)	Phase 2 completed	Multiple Phase 2 studies - 2x completed (in EU/PR) - 1 recruiting - 1 active, not recruiting
Duration of protection	100% seroconversion at **13 months** following single-dose administration	6 months	6 months
Phase 3 Guidance	**Pivotal trial (Phase 3) initiation planned Q2 2020**	2020	2020

1 PR Emergent BioSolutions Announces Interim Results From Phase 2 Study Evaluating CHIKV-VLP, Chikungunya Virus Vaccine Candidate (Link) + Detailed study results Emergent/Paxvax' Phase 2 clinical trial results (Link), **2** PR Themis Bioscience Publishes Compelling Phase 2 Results for Lead Vaccine Candidate against Chikungunya Fever in The Lancet (Link) + Themis' Phase 2 clinical trial results: (Link), **3** PR Valneva reports further positive results for its chikungunya vaccine candidate (Link),

VLA1553 key differentiators

The only single-shot vaccine candidate for chikungunya today

Rapid onset of long-lasting protection

- Single vaccination is sufficient to induce sustaining, high titer, neutralizing antibodies

Cross-protection potential against globally circulating strains

“Intrinsic human viral challenge” provided first indication of efficacy

Full-scale drug substance manufacturing process established at existing in-house FDA licensed facility

- Product is lyophilized, optimized storage conditions

A Surrogate of Protection[1] required for "Accelerated Approval" at FDA has already been established; EoP2 meeting scheduled for February 2020

Manufacturing and commercial infrastructure to produce and commercialize VLA1553 already in place

1 Immune marker reasonably likely to predict clinical benefit, as an immunogenicity endpoint in lieu of a clinical endpoint to infer vaccine effectiveness

Commercial Products

Successful commercial business has positioned Valneva to advance its R&D assets to late stage development

Commercial business overview

2019 FY Guidance

Direct sales[1]
86%

Gross margin[2]
65%

Aiming to increase product sales in private markets and to grow commercial business EBIT.

1 2019 9M actual, **2** Gross margin on product sales 2019 9M actual

IXIARO®/JESPECT®

Only vaccine against Japanese encephalitis (JE) in US, Canada and Europe

IXIARO®/JESPECT®

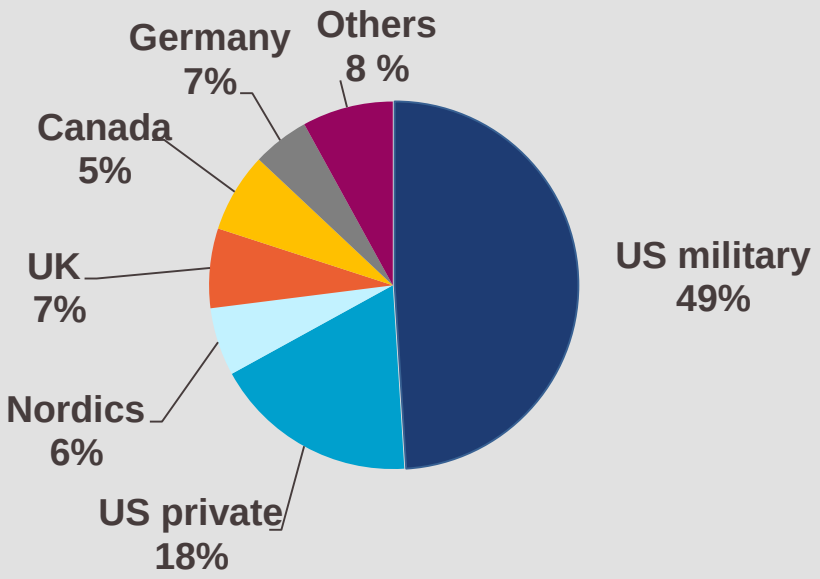
- **Designed to protect travelers and military against JE, the leading cause of viral neurological disease and disability in Asia**
- Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older[1]

Commercial position

- Currently, **no effective treatment for the disease**
- **The only approved vaccine available for US, EU and Canadian travelers**
- Supply agreement in place with US Military and strong track record of repeat contracts
- Limited competition - local producers exist in endemic regions and mainly serve public markets

US accounts for >65% of sales and growing

9M '19 product sales analysis



Growth expected to be 20% CER[2] or more in 2019

1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years of age. Prior to availability of the new presentation, no attempt should be made to adjust the syringe volume or to administer a 0.25mL/3µg dose in children less than 3 years of age.; **2** CER: at constant exchange rates

DUKORAL®

Only cholera (ETEC[1]) vaccine approved in EU, Canada and Australia

DUKORAL®

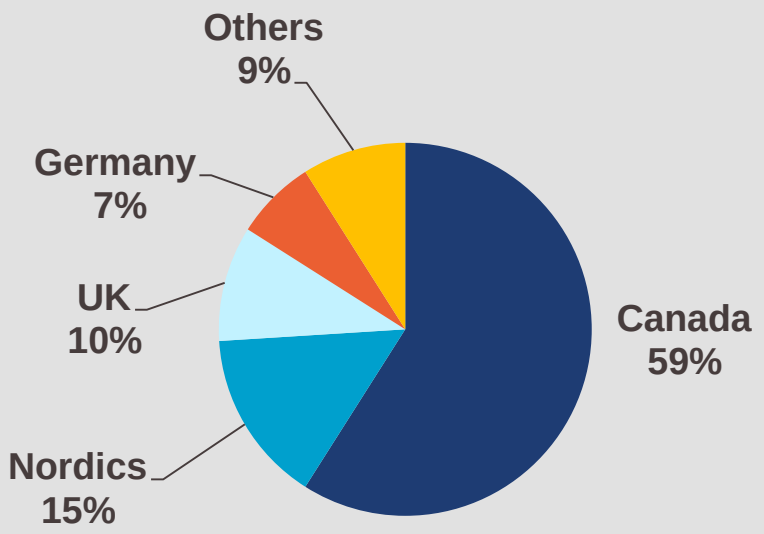
- **For the prevention of diarrhea caused by *Vibrio cholera* and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)**[1]
- **Designed to protect adults and children** traveling to endemic areas

Commercial position

- In several markets, incl. EU, indicated for cholera only
- **Only approved cholera vaccine available for Canadian, European and Australian travelers**
  - ~3-5 million cholera cases, 100,000-120,000 deaths/year[2]
  - ~5-18 million reported ETEC cases/year[3] (ETEC is the most frequent form of traveler's diarrhea)
  - WHO pre-qualification widely used in other countries
  - Asian manufacturers predominantly serve local markets

Canada accounts for over half of sales

9M '19 product sales analysis



Revenues to grow by up to 5% CER[4] in 2019

1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium; **2** WHO cholera factsheet February 2014; **3** Lundkvist J, Steffen R, Jonsson B. Cost-benefit of WC/rBS oral cholera vaccine for vaccination against ETEC-caused travelers' diarrhea. J Travel Med 2009; 16(1):28-34; **4** CER: at constant exchange rates

2019 product sales guidance raised following strong 9M results - underlying EBITDA growth diluted by one-time charges relating to GSK termination settlement

	2018	2019 Guidance
Product sales revenues	€103.5m	**€125m - €130m**
Total revenues	€113.0m	€125m - €130m
R&D investments	€25.3m	€35m - €40m
Gross margin	60.7%	65%[1]
Net operating margin[2]	24.1%	32%[1]
EBITDA	€13.1m	€5m - €10m

1 9M 2019 actual **2** Net operating margin is based on the P&L for the Commercial Products segment including an allocation (56%) of G&A costs from Corporate Overheads and Amortisation of Intangibles related to IXIARO®

Valneva's Management and Advisory Team – dedicated to deliver VLA's vision

Experienced international team

Management Board

Thomas Lingelbach
President & CEO

Franck Grimaud
President & CBO

David Lawrence
CFO

Wolfgang Bender, MD, PhD, *CMO*

Frédéric Jacotot
General Counsel & Corporate Secretary

Supervisory Board

- **Frédéric Grimaud** (France), *Chairman*
- **Lisa Shaw-Marotto** (US), *Vice Chairperson, Chair – Nomination & Compensation Committee*
- **James Sulat** (US), *Chair – Audit Committee*
- **Anne-Marie Graffin** (France)
- **Alexander von Gabain, Prof., PhD** (Austria)
- **Thomas Casdagli** (UK)
- **Sandra E. Poole** (US)

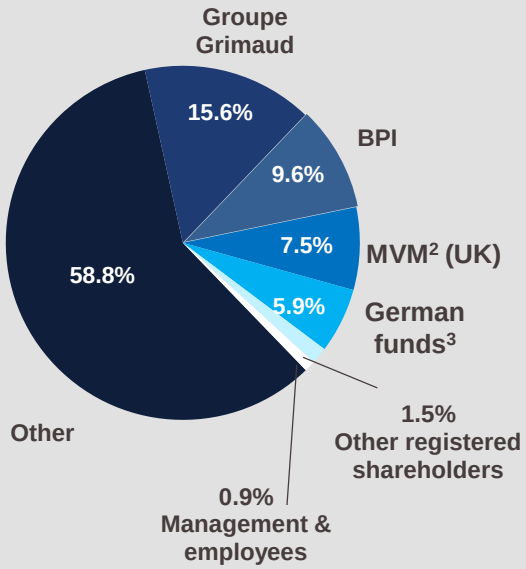
Scientific Advisory Board

- **Ralf Clemens, MD, Ph.D.,** *Chair*
- **Norman W. Baylor, Ph.D.**
- **Anna Durbin, MD**
- **Alain Munoz, MD, Ph.D.**
- **George R. Siber**
- **Stanley Plotkin, MD**

VLA has strengthened its institutional shareholder base with blue-chip healthcare investors including US

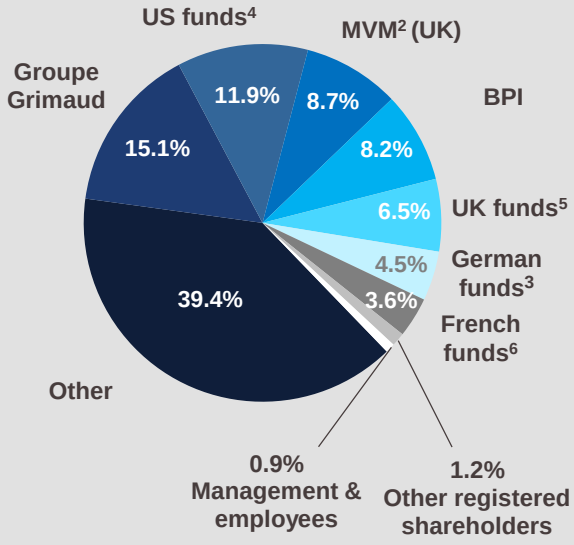
January 2018

- Number of ordinary shares: 77.6m
- Shareholder structure[1]:



November 2019

- Number of ordinary shares: 90.9m
- Shareholder structure[1]:



Capital strategy

- Leverage commercial business for debt/non-dilutive funding
- US remains best capital market for Lifesciences
- Nasdaq listing being contemplated

1 Estimates based on ordinary share capital; **2** Funds managed by MVM Life Science Partners; **3** Combined positions of Apus Capital, Apo AM, Lupus alpha, and others; **4** Combined positions of 11 U.S.-based funds managed by Deerfield Partners, Armistice Capital, Artisan Partners L.P., New Leaf, General American, Granite Point and others ; **5** Combined positions of Highclere, AXA Investment Managers Ltd. and Abingworth LLP; **6** Combined positions of 4 France-based funds managed by AXA Paris, CDC Entreprises Valeurs Moyennes, Eiffel Investment Group and Tocqueville Finance.

Upcoming newsflow

Chikungunya vaccine candidate VLA1553: EoP2 FDA meeting February 2020 with potential Phase 3 starting in Q2 2020

Full year financial results and guidance end February 2020

Lyme partnering process

Lyme disease vaccine candidate VLA15: Phase 2 initial data mid-2020

New IXIARO® contract with the U.S. Department of Defense expected H1 2020

Thank you
Merci
Danke
Tack

valneva

Appendices

INVESTOR MARKET SENTIMENTS GATHERED BY EURONEXT

PERCEPTION ON BIOTECHS - SECTORIAL TRENDS

MITIGATED PERCEPTION ON BIOTECHS – LOTS OF DISAPPOINTMENTS IN THE PAST MEAN INVESTORS ARE MORE CAUTIOUS & SELECTIVE
CLEAR DIFFERENCE MADE BETWEEN EUROPEAN & AMERICAN BIOTECHS

ALMOST 80% OF INVESTORS INTERROGATED HAVE A NEUTRAL TO NEGATIVE PERCEPTION ON THE CURRENT EVOLUTION OF THE BIOTECH SECTOR, ESPECIALLY IN FRANCE

- **Very poor track-record of the sector** in the past couple of years, with multiple clinical failures along the way. Investors are **more and more cautious** when its comes to **making investments decisions regarding the sector.**
- **Clear shift appeared regarding perception of the biotech sector in terms of geography** with a first distinction made between European and US biotech companies, then between European and French ones.
- On the positive side, the recent general downwards trend in share price has created new investment opportunities, **driving down valuations in Europe relative to the United States.**
- **Globally, investors become more and more selective** in companies and will primarily focus on **established, larger biotech companies** and the ones with **solid fundamentals** and **good technologies.**

FOCUS ON FRENCH BIOTECHS:

The sector has been severely hurt by the clinical disappointments experienced over the past 4 years by French biotech companies which had the potential to be sector-leaders in their respective fields, creating distrust within the investor community (ex. Pharnext, DBV, Cellectis …)

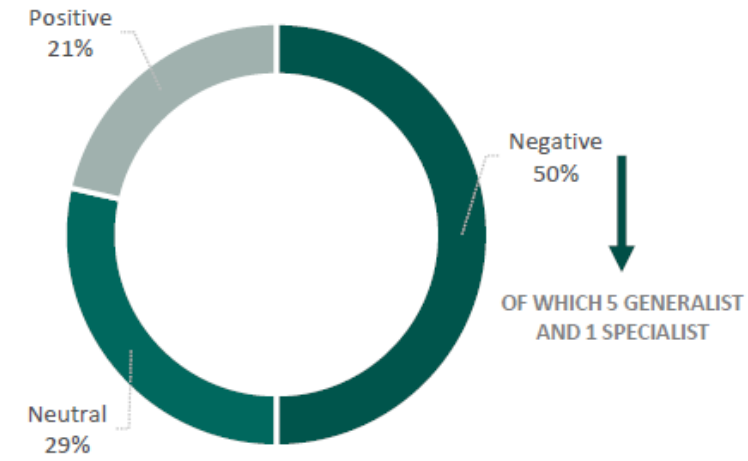
(i) **Absence of success stories in France compared to Belgium**, creating arbitrage investment opportunities towards companies like ArgenX, Mithra or Galapagos

(ii) Incapacity to **transform clinical success into commercial success**

(iii) French biotech universe composed mainly of **very-small companies with only 1 or 2 products in their pipeline**

GENERAL PERCEPTION OF THE BIOTECH SECTOR

In % of answers – 13 respondents



SELECTED CITATIONS

1. *« En ce moment et depuis un moment, je n'investis plus dedans. Je suis pas complètement sorti car j'ai encore du Nanobiotix par exemple, mais j'ai fait un gros nettoyage. »*
2. *"I think the European market is undervalued relative to the US. There is an increasing number of good and attractive opportunities in Europe"*
3. *« La perception générale, c'est qu'en résumé, c'est assez binaire »*

EURONEXT CORPORATE SERVICES

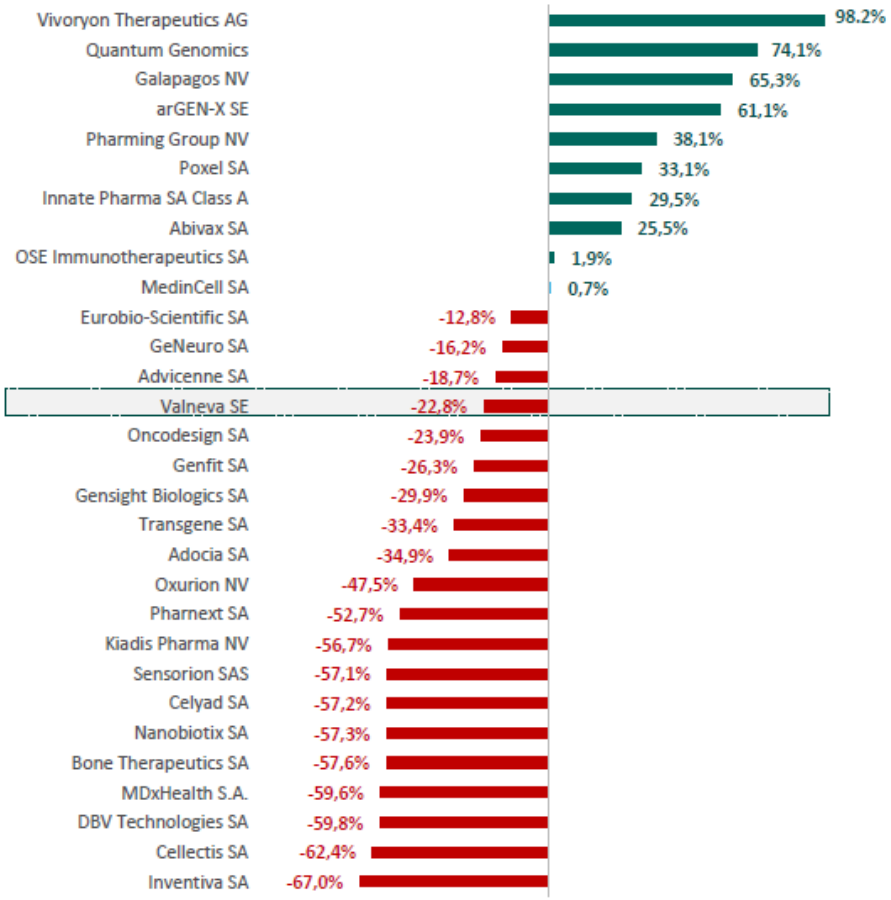
| Source: Euronext Post-Listing Advisory as of December 6th, 2019, based on a perception study conducted amont 14 generalist and healthcare specialist institutional investors

NEXT BIOTECH DETAILED PERFORMANCE OVER LAST 12 MONTHS

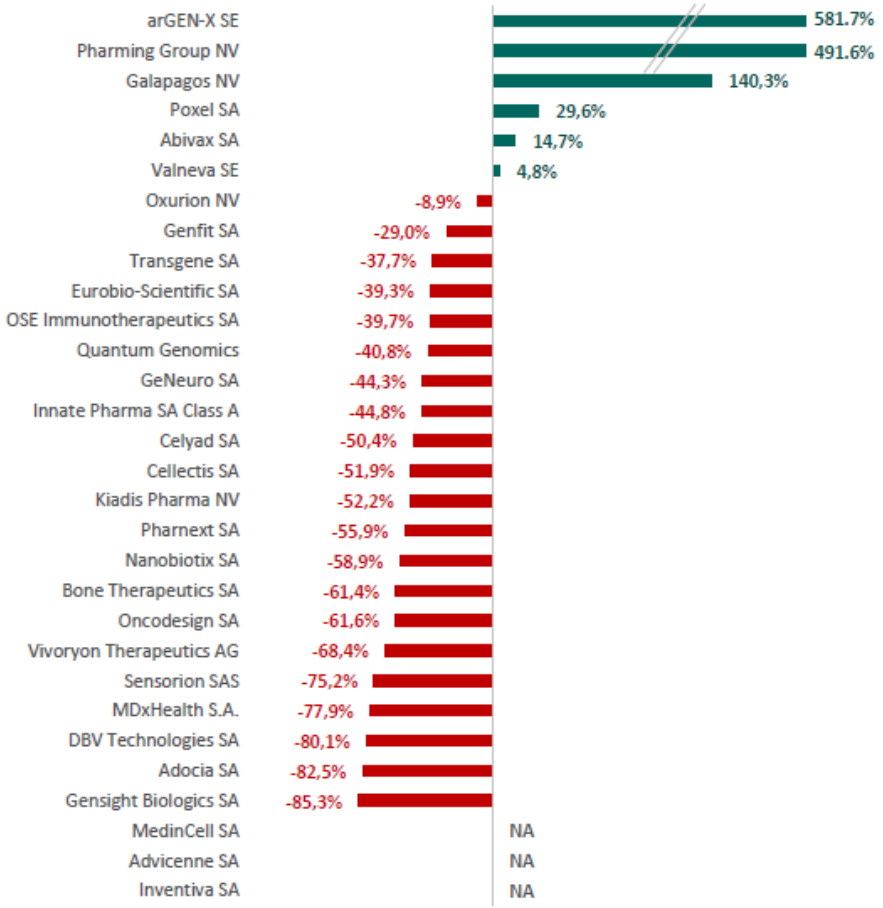
AS OF OCTOBER 10, 2019

Contrary to the +5.0% increase of the Next Biotech over the last 12 months, only 10 stocks have presented positive performance among the 48 stocks included in Next Biotech

TOP 30 NEXT BIOTECH | Individual Stock Performance overs last 12 months
As of October 10, 2019 – In euros



TOP 30 NEXT BIOTECH | Individual Stock Performance overs last 3 years
As of October 10, 2019 – In euros



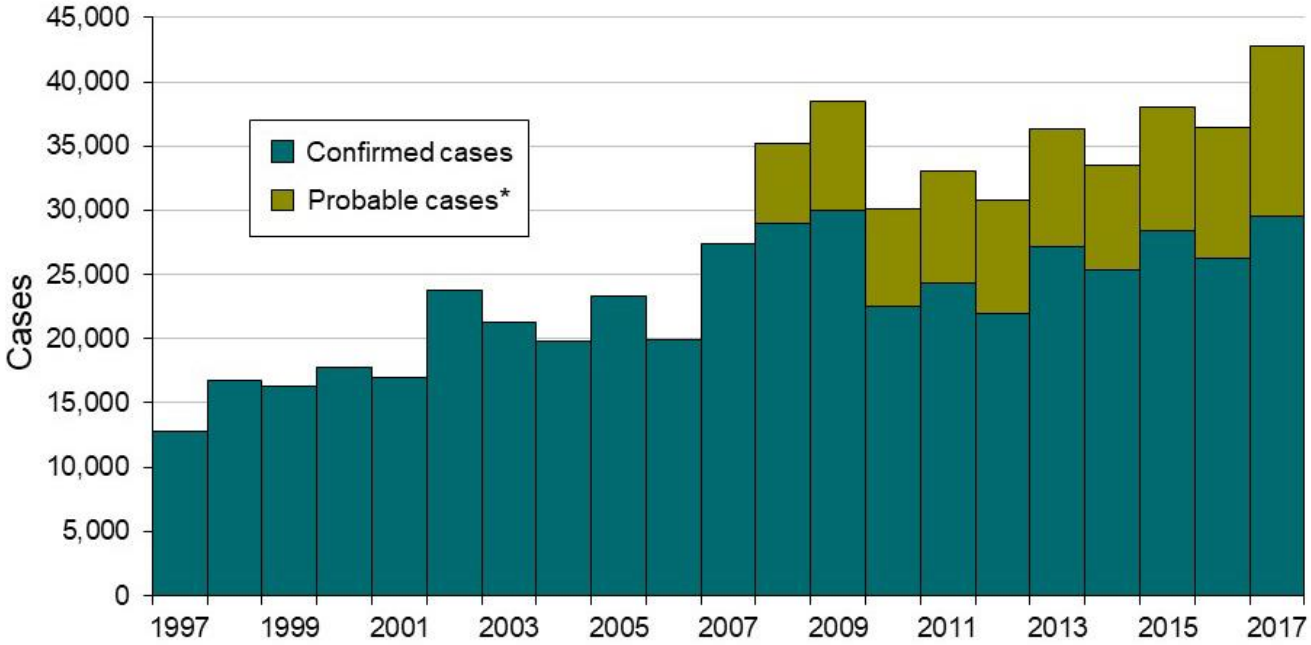
EURONEXT CORPORATE SERVICES

| Source: Factset as of 10-10-2019

Lyme disease epidemiology

Increased attack rate in endemic regions & endemic regions are expanding

Annual Reported Cases of Lyme Disease in the US[1]



- **Lyme disease has seen a marked increase in reported cases, driven by:**
  - Climate change contributing to increased tick and host populations
  - Longer tick breeding seasons
  - Increasing awareness and healthcare follow-ups

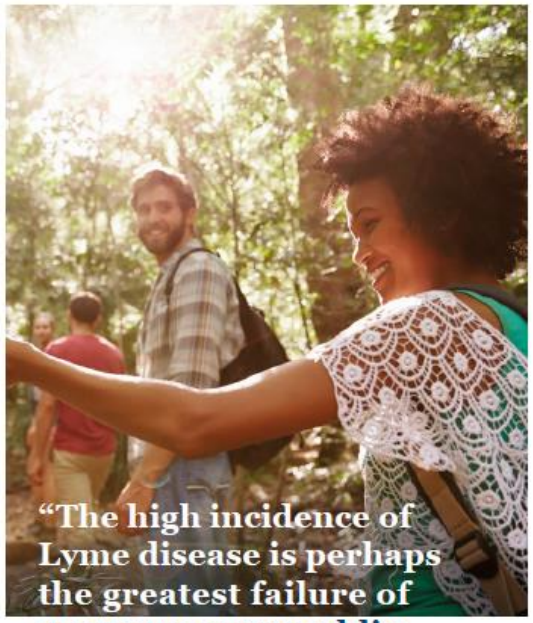
Estimated Cases

- **~ 300,000 cases in US (p.a.)[2]**
- **~ 200,000 cases in EU (p.a.)[3]**
- Most-affected US regions:
  - 95% of US cases in 2016 occurred in Northern US states
- Key age Groups:
  - 17.3% of cases occur in 5-14 years
  - 36.6% of cases occur in 40-64 years

1 https://www.cdc.gov/lyme/why-is-cdc-concerned-about-lyme-disease.html; 2 https://wwwnc.cdc.gov/eid/artickle/21/9/15-0417_article; 3 Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report; 4 Climate change influences on the annual onset of Lyme disease in the United States; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631020/;

Vaccination against Lyme disease

Justification for a Lyme vaccine



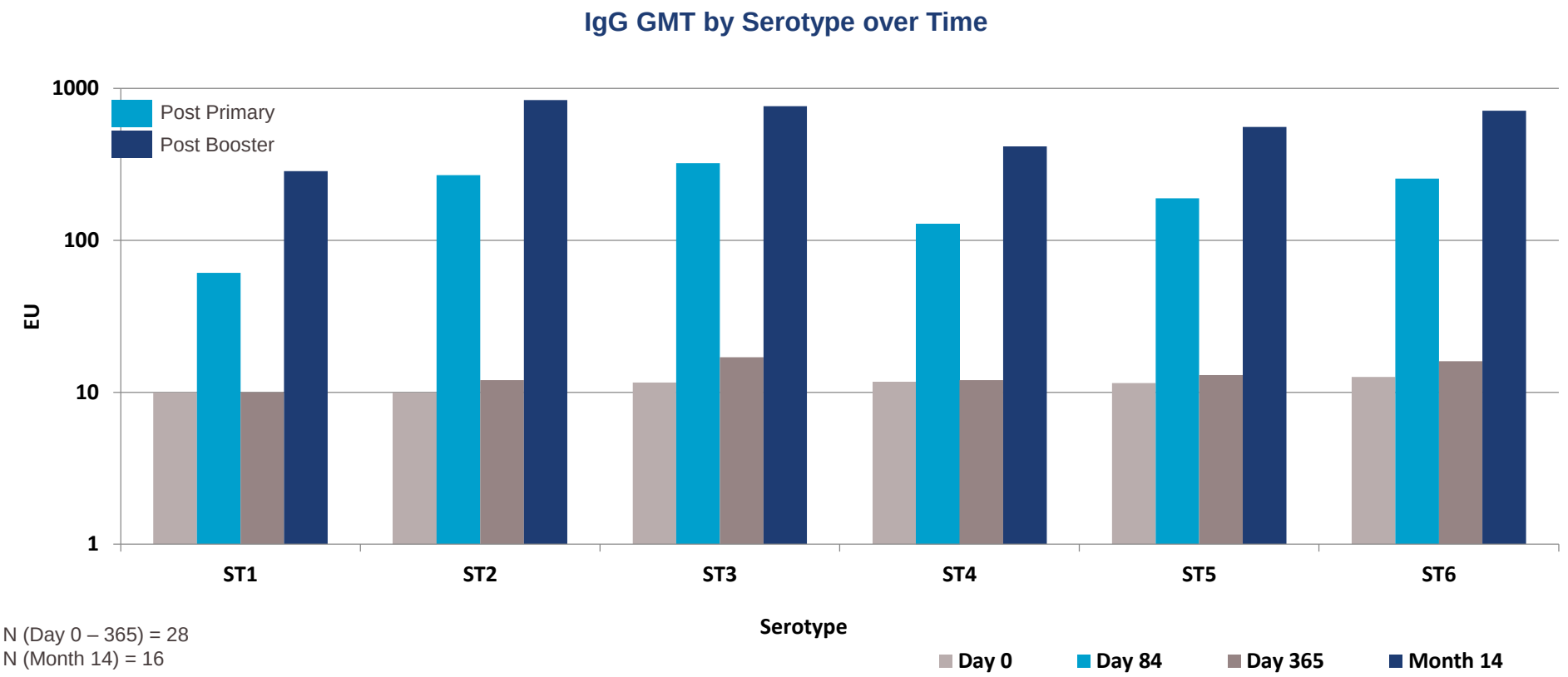
- Vaccination with OspA has been proven to work in the past (Lymerix®, ImuLyme®)
- **Disproven postulate[1], restrictive recommendations and corporate decisions resulted in there being no Lyme vaccine available for humans since 2002**
- **Delayed or inadequate treatment can lead to disabling sequelae**
- **Disease footprint widens[2]**
- **Direct medical costs in the US estimated up to $1.3 billion[3] – indicating an attractive health economical benefit**
- **Other preventive measures have not been shown to work on a public health scale**

1 Steere et al. CID 2011: 52 (Suppl3) S259; **2** New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/ ; **3** Adrion, E. et al PLOS ONE Feb 2015

Lyme Phase 1 study (VLA15-101) – Immunogenicity

GMT for highest adjuvanted dose group between 61 (ST1) and 269 (ST2), substantial booster effect

IgG GMT of Highest Adjuvanted Group (90µg + Alum) Before and After Primary Series and Booster Dose



N (Day 0 – 365) = 28
N (Month 14) = 16

Chikungunya: Vector prevalence and disease outbreaks

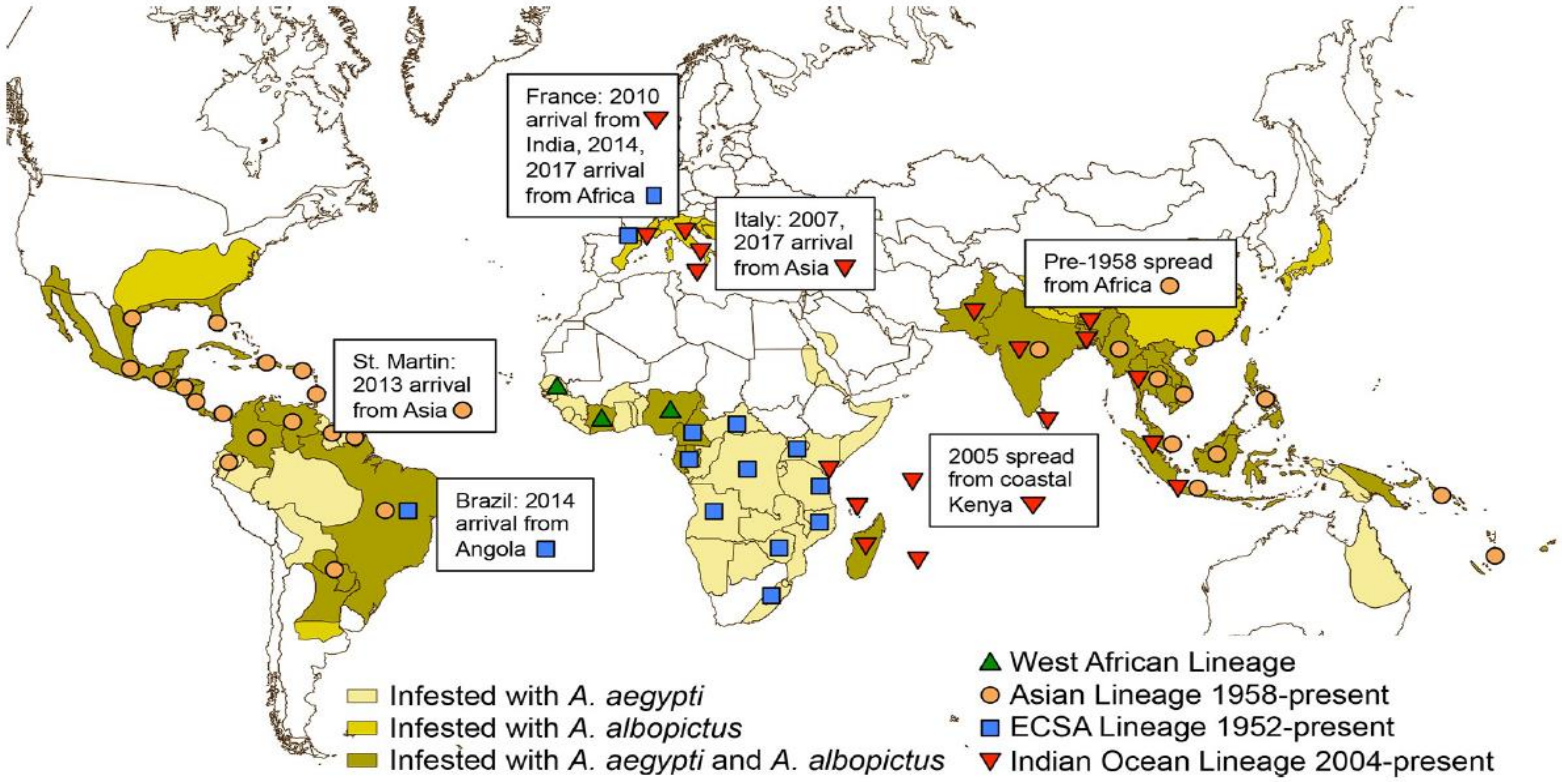


Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified. Data from World Health Organization (http://www.who.int/emergencies/diseases/chikungunya/en/) and Pan American Health Organization (https://www.paho.org/hq/index.php?option=com_topics&view=article&id=343&Itemid=40931&lang=en). CHIKV, chikungunya virus.

https://doi.org/10.1371/journal.pntd.0006919.g001

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