



COMBINED GENERAL MEETING DECEMBER 20, 2023

Summary on the Group situation during the past fiscal year



VALNEVA SE – SUMMARY ON THE GROUP SITUATION

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VALNEVA

A European company (*Societas Europaea* or SE) with a Management and a Supervisory Board

Share capital: €20,836,821.30

Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain (France)

Nantes Companies Register (RCS) No. 422 497 560

SUMMARY ON THE GROUP SITUATION DURING THE PAST FISCAL YEAR

1. SITUATION OF THE COMPANY AND THE GROUP AND ITS ACTIVITY DURING THE PAST FISCAL YEAR

1.1 Presentation of the Valneva Group

Valneva is a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. Valneva takes a highly specialized and targeted approach, applying its deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the world's first vaccine against the chikungunya virus, the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.



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1.2 2022 Annual operating highlights

See the translated excerpt of the Company's 2022 Universal Registration Document, on next pages.



1.1.2 Annual operating highlights

In 2022, Valneva achieved numerous major milestones:

Research & Development

(a) Valneva Completed BLA Submission to U.S. FDA for its Single-Shot Chikungunya Vaccine Candidate

On December 23, 2022, Valneva announced that it had completed rolling submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its single-shot chikungunya vaccine candidate, VLA1553. Valneva is seeking approval of its investigational chikungunya vaccine in persons aged 18 years and above.

Valneva had initiated the rolling submission of this application on August 18, 2022 following the publication of final Phase 3 data in March 2022 and the publication of final lot-to-lot consistency data in May 2022.

(b) Valneva Reported Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate

On December 5, 2022, Valneva reported positive antibody persistence data twelve months after vaccination with a single dose of its chikungunya vaccine candidate, VLA1553.

Valneva had initiated this trial (VLA1553-303) following the announcement of positive immunogenicity and safety data for the Phase 3 study VLA1553-301 in March 2022. It aims to follow a subset of 363 healthy adult participants for a period of at least five years and confirm the anticipated long-term durability of the antibody response after a single vaccination.

12 months after a single vaccination, 99% of participants retained neutralizing antibody titers above the seroresponse threshold of 150. These antibody levels confirm the antibody persistence profile observed in an earlier study. The antibody persistence was similar in older adults aged ≥ 65 years, who retained neutralizing antibody titers comparable to younger adults throughout the follow-up. These results follow completion of the pivotal study VLA1553-301, for which a seroresponse rate of 96% six months after vaccination¹ was reported. The study will continue to monitor antibody persistence on an annual basis.

No safety concerns were identified for the duration of the follow-up study, confirming the safety profile observed in previous studies.

(c) Valneva Successfully Completed Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate

On May 25, 2022, Valneva announced the successful completion of the lot-to-lot Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. The final analysis included six-month follow-up data and confirmed the topline results reported in December 2021.

The VLA1553-302 trial met its primary endpoint, demonstrating that three consecutively manufactured vaccine lots elicited equivalent immune responses measured by neutralizing antibody titer GMT ratios on Day 29 after vaccination.

The trial included 408 participants aged 18 to 45 years. The safety profile shown in study VLA1553-302 was similar to the Phase 3 trial, VLA1553-301. With a 96.0% seroprotection rate at Day 180, the immunogenicity profile from study VLA1553-301 was also confirmed.

(d) Valneva Successfully Completed Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate

On March 8, 2022, Valneva announced the successful completion of the Phase 3 pivotal trial of its single-shot chikungunya vaccine candidate, VLA1553. The positive final analysis included six-month follow-up data and confirmed the topline results reported in August 2021.

The VLA1553-301 trial, which enrolled 4,115 adults aged 18 years and above across 44 sites in the U.S., met all primary and secondary endpoints. The final analysis confirmed the very high level of seroprotection, with 98.9% of participants achieving protective levels of chikungunya virus (CHIKV) neutralizing antibodies one month after receiving a single vaccination (263 of 266 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 96.7-99.8). The excellent immunogenicity profile was maintained over time, with 96.3% of participants showing protective CHIKV neutralizing antibody titers six months after receiving a single vaccination (233 of 242 subjects from the per-protocol subgroup tested for immunogenicity, 95%CI: 93.1-98.3). The reported levels of seroprotection far exceeded the 70% threshold (for non-acceptance) based on a surrogate of protection agreed with the FDA under the accelerated approval pathway.

VLA1553 was also confirmed to be highly immunogenic in elderly study participants (65 years of age or older), who achieved equally high seroprotection rates and neutralizing antibody titers over time as younger adults. A dedicated antibody persistence trial (VLA1553-303) will monitor a subset of participants from study VLA1553-301 for a period of at least five years to confirm the anticipated long-term protection after a single vaccination.



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The six-month safety profile was also consistent with previous results across all age groups. VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The majority of solicited adverse events were mild or moderate and resolved within three days. 2.0% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia.

The initiation of this clinical trial was announced on January 31, 2022.

(e) Valneva and Pfizer Reported Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate

On December 1, 2022, Valneva and Pfizer reported antibody persistence data six months after the completion of a three-dose (Month 0-2-6) or a two-dose (Month 0-6) vaccination schedule with their Lyme disease vaccine candidate, VLA15 in both children and adults. This is the first time antibody persistence data are reported in pediatric populations for this vaccine candidate.

As observed in previous clinical studies with VLA15, antibody levels declined over time in all study groups but remained above baseline, confirming their persistence six months after completion of both vaccination schedules. Overall, antibody levels remained higher with the three-dose vaccination schedule compared to the two-dose schedule. Geometric mean fold rise (GMFRs) compared to baseline were 1.9-fold for Serotype 1 (ST1) to 3.2-fold Serotype 2 (ST2) across all age groups in the Month 0-2-6 vaccination schedule. The highest GMFRs were reported in the 5 to 11 years old age group, with GMFR levels at 2.8-fold (ST1) to 6.6-fold (ST2).

These results further validated the use of the three-dose vaccination schedule which is also included in the Phase 3 protocols for all participants.

No vaccine-related serious adverse events (SAEs) and no safety concerns were observed in this six-month observational follow up.

(f) Pfizer and Valneva Initiated Phase 3 Study of Lyme Disease Vaccine Candidate VLA15

On August 8, 2022, Valneva announced the initiation of a Phase 3 clinical study, Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524), to investigate the efficacy, safety and immunogenicity of their investigational Lyme disease vaccine candidate, VLA15.

The study is being conducted at up to 50 sites located in areas where Lyme disease is highly endemic, including Finland, Germany, the Netherlands, Poland, Sweden and the United States. Participants will receive three doses of VLA15 180 µg or saline placebo as a primary vaccination series followed by one booster dose of VLA15 or saline placebo (1:1 ratio).

As per the terms of the collaboration agreement between Pfizer and Valneva, Pfizer made a \$25 million milestone payment to Valneva upon initiation of the Phase 3 study.

(g) Valneva and Pfizer Reported Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate

On April 26, 2022, Valneva and Pfizer reported positive Phase 2 pediatric data for their Lyme disease vaccine candidate, VLA15.

The Phase 2 trial, VLA15-221, was the first clinical study with VLA15 to enroll a pediatric population (5-17 years old). It compared the immunogenicity and safety of VLA15 after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was found to be more immunogenic than in adults with both vaccination schedules tested.

These data build on the strong immunogenicity profile already reported for adult participants (18-65 years old) in February 2022.

Like in adults, the immunogenicity and safety data support a three-dose primary vaccination schedule in pediatric participants in the Phase 3 study.

(h) Valneva and Pfizer Reported Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate

On February 4, 2022, Valneva and Pfizer reported further positive Phase 2 data for their Lyme disease vaccine candidate, VLA15. Based on these new results, Valneva and Pfizer decided to proceed with a three-dose primary series vaccination schedule in their Phase 3 clinical trial.

The Phase 2 trial, VLA15-221, compared the immunogenicity of VLA15 after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In the sub-analysis of adult participants (18-65 years old) who received VLA15 in either the two-dose schedule (N=90) or the three-dose schedule (N=97), performed one month after the last vaccination dose, VLA15 was found to be immunogenic with both vaccination schedules tested. These data are consistent with the strong immunogenicity profile observed for this age group in previous Phase 2 studies. However, the induction of anti-OspA IgG (anti-outer surface protein A immunoglobulin G) antibody titers was higher in participants who received the three-dose primary series compared to those who received the two-dose primary series, supporting the use of a three-dose primary series schedule in the planned Phase 3 clinical trial.

The analysis was also consistent with the acceptable safety and tolerability profile observed in previous studies of VLA15. No vaccine-related serious adverse events (SAEs) were observed.



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(i) Valneva Reported Further Heterologous Booster Data for its Inactivated COVID-19 Vaccine

On December 30, 2022, Valneva reported further heterologous booster data from an exploratory, small clinical study for its inactivated COVID-19 vaccine, VLA2001.

In study VLA2001-307, a subset of participants (three out of nine groups) received VLA2001 following two or three doses of mRNA COVID-19 vaccine, with or without breakthrough infection (25-50 participants per group).

The data show that a booster dose of VLA2001 was well tolerated in previously BNT162b2 (Pfizer/BioNTech)- or mRNA 1273 (Moderna)-vaccinated participants, confirming the favorable safety profile of VLA2001 seen across all studies – including in homologous or heterologous booster settings. However, in this study, an additional booster dose of VLA2001 elicited only a marginally increased neutralizing antibody response. The Company previously reported positive heterologous booster results following primary vaccination with ChAdOx1-S (AstraZeneca) in August 2022 and positive homologous booster results at the end of December 2021.

The study had been initiated on May 4, 2022.

(j) Valneva Announced Publication of its COVID-19 Vaccine Phase 3 Data in The Lancet Infectious Diseases

On September 6, 2022, Valneva announced that *The Lancet Infectious Diseases* (“The Lancet ID”), a peer-reviewed medical journal, had published the Company’s pivotal Phase 3 clinical data for its inactivated, whole-virus COVID-19 vaccine, VLA2001.

The paper, entitled “Immunogenicity and safety of an inactivated whole-virus COVID-19 vaccine (VLA2001) compared with the adenoviral vector vaccine ChAdOx1 in adults in the UK (COV-COMPARE): interim analysis of a randomised, controlled, Phase 3, immunobridging trial” provides a detailed analysis of the Phase 3 results, showing that VLA2001 demonstrated superior neutralizing antibody titer levels versus the comparator vaccine, as well as broad T-cell responses against the S- (spike), M- (membrane), and N- (nucleocapsid) proteins, and a significantly better tolerability profile versus the comparator vaccine.

(k) Valneva Reported Further Positive Phase 3 Immunogenicity and First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001

On August 29, 2022, Valneva reported further positive Phase 3 results for its inactivated, adjuvanted COVID-19 vaccine VLA2001. Additional readouts from the Company’s pivotal VLA2001-301 “Cov-Compare” trial showed persistent immunogenicity and first positive

heterologous booster results following primary vaccination with ChAdOx1-S (AstraZeneca).

The Company previously reported immunogenicity data at Day 43 post primary vaccination and has now evaluated immunogenicity in VLA2001-301 trial participants approximately two months following primary immunization (“Day 71”), as part of the prespecified analysis of secondary endpoints. At Day 71, neutralizing antibody titers induced by VLA2001 were non-inferior to ChAdOx1-S: VLA2001 GMT was 444.0 (95% CI: 414.0, 476.2), ChAdOx1-S GMT was 411.8 (95% CI: 389.7, 435.0). Seroconversion rates remained constant at Day 71 (above 92% in both treatment groups). Additionally, T-cell responses analyzed in a sub-set of the 3,560 trial participants followed for approximately six months after primary vaccination (“Day 208”) showed that VLA2001 induced broad antigen-specific IFN-gamma producing T-cells reactive against the S-protein, as well as the N- and M-proteins up to Day 208. The safety profile of VLA2001 continues to be favorable and the vaccine was well tolerated up to Day 208.

The occurrence of COVID-19 cases (exploratory endpoint) was similar between the VLA2001 and ChAdOx1-S groups, supporting earlier findings. There were no severe COVID-19 cases up to Day 208 in the direct comparative groups (above 30 years of age), which may suggest that both vaccines provided similar protection against severe COVID-19 disease caused by the circulating variant(s) (predominantly Delta). There was one severe COVID-19 case in the 18-29 years of age cohort (n=1040 participants) in a participant with a BMI >40 and history of asthma.

A total of 958 participants from the VLA2001-301 trial received a single dose of VLA2001 approximately eight months after priming with either VLA2001 or ChAdOx1-S (AstraZeneca) to evaluate the booster effect in both homologous and heterologous (“mix and match”) settings. Previously, VLA2001 showed an excellent immune response after a third dose administered seven to eight months in participants who received VLA2001 as a primary vaccination in a Phase 1/2 study.

In both the homologous and heterologous setting, VLA2001 was able to boost immunity to higher neutralizing antibody titers than following priming, and to levels reported to be highly efficacious (90%) against SARS-CoV-2. Neutralizing antibody titers following a VLA2001 booster dose administered approximately eight months after primary vaccination were between 3-fold (heterologous) to 28-fold (homologous) higher compared to pre-boost levels, in line with previous VLA2001 Phase 1/2 homologous booster results. A booster dose of VLA2001 was well tolerated by both VLA2001- and ChAdOx1-S-primed participants. The tolerability profile of a booster dose with VLA2001 was similar to the favorable profile observed after the first and second vaccination with VLA2001 in the Phase 1/2 and initial Phase 3 trial results.

Initiation of the “Cov-Compare” trial had been announced on January 25, 2022.



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(l) Valneva Confirmed WHO Recommendations for its Inactivated COVID-19 Vaccine

On August 23, 2022, Valneva confirmed that the World Health Organization (WHO) had issued recommendations for use of the Company's inactivated COVID-19 vaccine.

WHO's interim recommendations for use of the Valneva VLA2001 vaccine were developed on the basis of advice issued by the Strategic Advisory Group of Experts on Immunization (SAGE) on its August 11, 2022 extraordinary meeting and published in its background document.

WHO's interim recommendations also included a recommendation for a booster dose of VLA2001 four to six months after completion of the primary series and note that a booster dose of VLA2001 following primary vaccination with ChAdOx1-S (AstraZeneca) can be considered.

(m) Valneva Received Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001

On June 24, 2022, Valneva announced that the European Commission (EC) had granted marketing authorization in Europe for Valneva's inactivated whole-virus COVID-19 vaccine, VLA2001, for use as primary vaccination in people from 18 to 50 years of age.

With this approval, VLA2001 became the first COVID-19 vaccine to receive a standard marketing authorization in Europe. The marketing authorization covers all 28 European Union Member States as well as Iceland, Liechtenstein, and Norway.

This marketing authorization followed recommendations from the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) on June 23, 2022.

(n) Valneva Received Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine

On May 16, 2022, Valneva announced that the United Arab Emirates (UAE) granted emergency use authorization for Valneva's inactivated, adjuvanted COVID-19 vaccine, VLA2001.

(o) Valneva Received Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine

On April 14, 2022, Valneva announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom had granted Conditional Marketing Authorization (CMA) for its inactivated whole-virus COVID-19 vaccine candidate, VLA2001, for primary immunization in adults 18 to 50 years of age.

(p) Valneva Received Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001

On March 1, 2022, Valneva announced that the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain has granted emergency use authorization for Valneva's inactivated, adjuvanted COVID-19 vaccine, VLA2001. This authorization follows a rolling review process with the Bahraini NHRA and reflects the NHRA's initiative to support the authorization of COVID-19 vaccines.

(q) Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant

On January 19, 2022, Valneva announced results from an initial laboratory study demonstrating that serum antibodies induced by three doses of Valneva's inactivated COVID-19 vaccine candidate, VLA2001, neutralize the Omicron variant.

Sera from 30 participants in the Phase 1/2 trial VLA2001-201 were used in a pseudovirus assay to analyze neutralization of the ancestral SARS-CoV-2 virus as well as the Delta and Omicron variants.

All 30 samples (100%) presented neutralizing antibodies against the ancestral virus and Delta variant, and 26 samples (87%) presented neutralizing antibodies against the Omicron variant. The mean fold reduction of neutralization relative to the ancestral virus was 2.7-fold for Delta and 16.7-fold for Omicron.

Commercial Activities

(r) Valneva and VBI Vaccines Announced European Partnership for Marketing and Distribution of PreHevbri®

On September 8, 2022, Valneva and VBI Vaccines announced a partnership in select European markets for the marketing and distribution of PreHevbri® [Hepatitis B vaccine (recombinant, adsorbed)], the only 3-antigen hepatitis B vaccine approved in Europe.

Under the terms of the agreement, Valneva has been promoting and distributing PreHevbri throughout select European countries, including the United Kingdom, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands since early 2023.

(s) Valneva Provided Update on IXIARO® Supply Contract with U.S. Department of Defense

On August 18, 2022, Valneva announced that the U.S. Department of Defense (DoD) had decided not to exercise the second option year of the contract to supply Valneva's Japanese encephalitis (JE) vaccine, IXIARO®.



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Due to the impact of the COVID-19 pandemic on its operations, the DoD considered its existing IXIARO® supply levels sufficient to meet current needs. The DoD had communicated an interest in negotiating a new supply contract in 2023, once inventory returns to standard levels. The Company expected no impact on its 2022 financial guidance as a result of this decision and continued deliveries of IXIARO® pursuant to the terms of the first option year, which the DoD exercised with amended terms, through the fourth quarter of 2022. The DoD has relied on IXIARO® since 2010 to help protect personnel who are deployed to JE endemic areas, for whom JE vaccination is recommended.

The total minimum value of the existing supply contract was approximately \$118 million, assuming the exercise of the second option year, which had a minimum value of approximately \$36 million for 250,000 doses.

(t) Valneva Confirmed Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine

On August 1, 2022, Valneva confirmed the signing of the amendment to its Advance Purchase Agreement (APA) with the European Commission (EC), following expiration of the Member States' opt-out period, as announced by the Company on July 20, 2022. Under this amendment, the Member States' purchases of VLA2001, Valneva's inactivated whole-virus COVID-19 vaccine, consisted of 1.25 million doses of VLA2001 in 2022, with the option to purchase an equivalent quantity later this year for delivery in 2022.

(u) Valneva Received Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement

On May 16, 2022, Valneva announced that it had received a notice from the European Commission ("EC") of intent to terminate the advance purchase agreement ("APA") for Valneva's inactivated whole-virus COVID-19 vaccine candidate VLA2001.

The APA provided the EC with a right to terminate the APA if VLA2001 had not received a marketing authorization from the European Medicines Agency ("EMA") by April 30, 2022. Based on the terms of the APA, Valneva had 30 days from May 13, 2022 to obtain a marketing authorization or propose an acceptable remediation plan.

The Company worked with the EC and the participating EC member states to agree to a remediation plan and to make VLA2001 available to those member states who still wish to receive it.

(v) Valneva Announced Closing of Upsized €102.9 Million Global Offering

On October 4, 2022, Valneva announced the closing of its previously announced global offering to specified categories of investors of an aggregate 21,000,000 new ordinary shares, consisting of a public offering of 375,000 American Depositary Shares ("ADSs"), each representing two ordinary shares, in the United States at an offering price of \$9.51 per ADS (the "U.S. Offering"), and a concurrent private placement of 20,250,000 ordinary shares in Europe (including France) and other countries outside of the United States at the corresponding offering price of €4.90 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately €102.9 million (\$99.9 million).

(w) Valneva Established an At-the-Market (ATM) Program on Nasdaq

On August 15, 2022, Valneva announced that it had filed a prospectus supplement with the U.S. Securities and Exchange Commission ("SEC") relating to an At-the-Market offering (the "ATM Program"). Pursuant to this financing program, the Company may offer and sell, including with unsolicited investors who have expressed an interest, a total gross amount of up to \$75.0 million of American Depositary Shares ("ADSs"), each ADS representing two of the Company's ordinary shares, from time to time in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, and pursuant to the terms of an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies"), acting as sales agent, subject to French regulatory limits. The timing of any sales will depend on a variety of factors and the Company is not under any obligation to utilize the ATM Program in a specified amount or at all.

(x) Valneva and Pfizer Announced Closing of Equity Investment

On June 23, 2022, Valneva and Pfizer announced the closing of the equity investment announced on June 20, 2022.

Pursuant to an Equity Subscription Agreement, Pfizer invested €90.5 (\$95) million in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase. Valneva is planning to use the proceeds to support its contribution to the planned Phase 3 development program for Lyme disease vaccine candidate VLA15.



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(y) Valneva Announced Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed

On April 26, 2022, Valneva announced an agreement to increase the principal amount of its existing \$60 million debt financing agreement with funds managed by leading US-based healthcare investment firms Deerfield Management Company and OrbiMed. This extension provided Valneva immediate access to \$20 million, with an additional \$20 million available upon potential conditional approval of its inactivated COVID-19 vaccine candidate, VLA2001, by the European Medicines Agency. The increased funding was used to further invest in R&D, including market access preparations for Valneva's chikungunya vaccine candidate, VLA1553.

(z) Valneva Awarded Up to £20 Million by Scottish Enterprise to Advance Vaccine Development

On February 21, 2022, Valneva announced that its subsidiary Valneva Scotland had been awarded research and development funding of up to £20 million by Scottish Enterprise.

The investment from Scotland's national economic development agency followed advanced discussions reported on December 23, 2021, and is comprised of two grants, which build on the agency's longstanding engagement with Valneva and will benefit the Company's manufacturing site in Livingston.

The first grant of up to £12,500,000 was to support research and development related to the manufacture of VLA2001, Valneva's inactivated, whole virus COVID-19 vaccine candidate. The second grant of up to £7,500,000 is to support research and development connected to Valneva's manufacturing processes for other vaccines.

Appointments

(aa) Valneva Appointed Dopal Patel as Chief Commercial Officer

On November 17, 2022, Valneva announced the appointment of Dopal Patel as Chief Commercial Officer (CCO) and Management Board member. With this newly created role, Valneva strengthened its management team with a recognized commercial industry leader as the Company advances its chikungunya vaccine candidate towards potential market entry in 2023.

Ms. Patel is an established commercial leader with over 23 years of experience in the pharmaceutical sector covering commercial strategy, execution, market access and lifecycle management. Over her career, she has held roles of increasing responsibilities across multiple countries including the United States, Australia, Belgium, Singapore, Thailand, and the European and emerging markets regions. Since 2019, Ms. Patel has been Global Commercial

Head of GSK's shingles vaccine (Shingrix®), leading a global cross-functional team establishing it as a global brand with significant worldwide expansion.

(bb) Valneva Appointed Dr. Thomas Decker and Dr. Michael Pfeleiderer to its Scientific Advisory Board

On May 31, 2022, Valneva announced the appointment of leading vaccine experts Dr. Thomas Decker and Dr. Michael Pfeleiderer to its Scientific Advisory Board (SAB).

Others

(cc) Valneva and Pfizer Entered into an Equity Subscription Agreement and Updated the Terms of their Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15

On June 20, 2022, Valneva and Pfizer announced that they had entered into an Equity Subscription Agreement and have updated the terms of their Collaboration and License Agreement for Lyme disease vaccine candidate VLA15.

As part of the Equity Subscription Agreement, Pfizer invested €90.5 (\$95) million in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase to further support the strategic Lyme partnership between the two companies.

In addition, Valneva and Pfizer updated the terms of their collaboration and license agreement which they announced on April 30, 2020. Valneva will now fund 40% of the remaining shared development costs compared to 30% in the initial agreement. Pfizer will pay Valneva tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement. In addition, the royalties will be complemented by up to \$100 million in milestones payable to Valneva based on cumulative sales. Other development and early commercialization milestones are unchanged, of which \$168 million remain, including a \$25 million payment to Valneva received upon Pfizer's initiation of the Phase 3 study.

(dd) Valneva Provided a Further Update on its COVID-19 Activities

On September 26, 2022, Valneva announced a further update on its COVID-19 vaccine activities.

The Company had previously communicated that it would invest in further development of a potential second-generation COVID-19 vaccine only if it received the necessary funding or commitments to such funding during the third quarter of 2022. At the time of the announcement, the Company was in active discussions with a prospective partner to potentially obtain such funding. These discussions may not lead to an agreement.



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(ee) Valneva and IDT Biologika Agreed on the Termination of their COVID-19 Collaboration

On September 16, 2022, Valneva and IDT Biologika announced they had agreed to terminate their collaboration following the delivery of inactivated COVID-19 bulk vaccine to Valneva, and considering order levels and existing inventories.

As per the commercial manufacturing services agreement signed in November 2021, IDT Biologika produced VLA2001 bulk vaccine at its Biosafety Level 3 facilities in Germany, and Valneva bought the batches that were already manufactured by IDT. In light of the reduced European Commission order, Valneva had suspended manufacturing of the vaccine and, as compensation, paid IDT €36.2 million in cash and the equivalent of €4.5 million in kind, in the form of specified equipment purchased by Valneva.

(ff) Valneva Announced Settlement Agreement with the UK Government

On June 15, 2022, Valneva announced that it had entered into a settlement agreement with the Government of the United Kingdom (“HMG”) in relation to the termination of the supply agreement for Valneva’s COVID-19 vaccine candidate, VLA2001.

The Company had announced, on September 13, 2021, that it had received a termination notice from HMG, and the termination, which Valneva accepted on the basis of HMG’s discretionary right to terminate for convenience, became effective on October 10, 2021.

The settlement agreement resolved certain matters relating to the obligations of the Company and HMG following the termination of the supply agreement and in relation to the separate agreement relating to clinical trials of VLA2001 in the United Kingdom, which remains in place.

The Company continues to have certain other obligations pursuant to provisions of the supply agreement that survive its termination.

(gg) Valneva Joined Euronext’s Tech Leaders Index

On June 8, 2022, Valneva announced its inclusion in the Euronext Tech Leaders Index which was launched yesterday by Euronext.

The Euronext Tech Leaders Index is composed of more than 100 European tech companies, which were identified by Euronext either to be leaders in their field or to have a particularly strong growth profile. It aims to strengthen the European tech sector and be a catalyst for the next generation of tech leaders.

[...]



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1.3 Recent events

Information on the Company's affairs since the beginning of the current fiscal year is presented in Section 1.1.3 of the Company's 2022 Universal Registration Document (see *the translation on next pages*).

Since the filing of the Company's 2022 Universal Registration Document, the following major events have occurred:

- + Publication of first quarter 2023 financial results;
- + Filing for Chikungunya Vaccine Authorization with Health Canada;
- + Publication of Valneva's Chikungunya Vaccine Candidate Phase 3 Data in The Lancet ;
- + Successful Outcome of Valneva's AGM and Appointment of Pfizer's Former Vaccine R&D Head to the Company's Supervisory Board;
- + Recommendation by the Supervisory Board to Transition from a Two-Tier Governance Model to a Board of Directors;
- + PDUFA Date Extension for Valneva's Chikungunya Virus Vaccine Candidate;
- + Extension of Existing Loan Agreement executed between Valneva and the funds managed by leading U.S. healthcare investment firms Deerfield Management Company and OrbiMed;
- + Positive Initial Phase 3 Safety Data in Adolescents for Valneva's Single-Shot Chikungunya Vaccine Candidate;
- + Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review;
- + Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for their Lyme Disease Vaccine Candidate;
- + Publication of Half Year 2023 Financial Results;
- + New IXIARO® Supply Contract with the U.S. Government Worth a Minimum of \$32 Million;
- + Valneva to Present on Chikungunya at Several Leading Scientific Conferences;
- + Submission of Chikungunya Vaccine Marketing Application to EMA and CHMP Accelerated Assessment;
- + Publication of Nine-Month 2023 Financial Results;
- + U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® ;
- + Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for Valneva's Single-Shot Chikungunya Vaccine Candidate;
- + Availability of Documentation for Valneva's Combined General Meeting of December 20, 2023 including Planned Changes to its Future Board of Directors.

Please refer to the Company's website www.valneva.com ("Media" / "Press Releases" section) for a detailed description of these latest events.



[...]

1.1.3 Recent events

Since the beginning of 2023, Valneva has made the following announcements.

(a) FDA Accepted Valneva's Chikungunya Vaccine License Application for Priority Review

On February 20, 2023, Valneva announced that the U.S. Food and Drug Administration (FDA) has completed a filing review of its Biologics License Application for Valneva's single-shot chikungunya vaccine candidate VLA1553 and has determined that the application is sufficiently complete to permit a substantive review. The review classification is Priority.

VLA1553 has been assigned a Prescription Drug User Fee Act (PDUFA) review goal date at the end of August 2023, which is the date by which the FDA intends to take action on the application. The FDA's acknowledgement of filing does not mean that a license will be granted, nor does it represent any evaluation of the adequacy of the data submitted.

(b) Valneva Completed Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate

On February 14, 2023, Valneva announced that it completed enrollment and vaccination for a Phase 3 trial in adolescents, VLA1553-321, of its single-shot chikungunya vaccine candidate, VLA1553. First results of the trial are expected mid-2023.

Funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the VLA1553-321 adolescent trial is intended to support the label extension in this age group following a potential initial regulatory approval in adults from the Food and Drugs Administration (FDA) in the United States (U.S).

Valneva completed rolling submission of the Biologics License Application (BLA) to the U.S. FDA for approval of VLA1553 in persons aged 18 years and above in December 2022. If BLA filing is accepted and approved, VLA1553 could become the first chikungunya vaccine to be marketed in the U.S.

The VLA1553-321 adolescent trial is also expected to support licensure of the vaccine in Europe and Brazil, which would be the first potential approval for use in endemic populations.

Conducted in collaboration between Instituto Butantan and Valneva, VLA1553-321 is a double-blinded, multi-center, randomized and placebo-controlled Phase 3 trial. 754 adolescents aged 12 to 17 years were vaccinated following randomization at a 2:1 ratio to receive either VLA1553 or placebo. The primary objective of the trial is to evaluate safety and immunogenicity 28 days following a single vaccination with VLA1553. Participants will be evaluated for the primary endpoint and followed up to twelve months. The study will also provide the first systematic safety and immunogenicity data in participants previously exposed to chikungunya.



VALNEVA SE – SUMMARY ON THE GROUP SITUATION

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(c) Pfizer and Valneva Issued Update on Phase 3 Clinical Trial Evaluating Lyme Disease Vaccine Candidate VLA15

On February 17, 2023, Valneva and Pfizer announced that Pfizer, as the study sponsor, had decided to discontinue a significant percentage of participants in the U.S. who had been enrolled in the Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524) Phase 3 clinical study. The study is investigating the efficacy, safety and immunogenicity of an investigational Lyme disease vaccine candidate, VLA15. These study participants, representing approximately half of the total recruited participants in the trial, are being discontinued following violations of Good Clinical Practice (GCP) at certain clinical trial sites run by a third-party clinical trial site operator. The discontinuation of these participants was not due to any safety concerns with the investigational vaccine and was not prompted by a participant-reported adverse event.

GCP is the international ethical and scientific quality standard for clinical trials that all clinical researchers need to follow. These standards are designed to put participants' interests first and ensure high scientific integrity. Once Pfizer learned of potential violations of GCP, it conducted a thorough review of the operations and data collection at the clinical trial sites run by the third party and followed standard operating safeguards to determine the correct course of action.

The clinical trial remains ongoing with other sites not operated by the third party, and Pfizer continues to enroll new participants at those sites. The companies intend to work with regulatory authorities, and as previously announced,^{1,2} aim for Pfizer to potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) in 2025, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

Participants are being notified and Pfizer has also notified the FDA, other regulatory agencies and the independent Institutional Review Board for this study.

Integrity of data collected in clinical trials is critical to provide evidence and confidence in a potential vaccine or medicine's safety and efficacy. Pfizer and Valneva are committed to collecting robust data needed for potential regulatory submission of VLA15. While VLA15 is still under investigation, to date the companies have been encouraged by the data from the Phase 2 clinical studies, which demonstrated strong immunogenicity and acceptable safety and tolerability profiles.

(d) Valneva Provided Clinical and Regulatory Updates for its COVID-19 Vaccine VLA2001

On March 2, 2023, Valneva announced additional data from remaining clinical studies and an update on regulatory submissions for its inactivated COVID-19 vaccine, VLA2001. As previously announced, Valneva will not invest in further development of the vaccine, in the absence of a new partnership. It is, however, completing remaining clinical studies and submissions as agreed with regulators.

On February 23, 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for the use of VLA2001 in adults 18 to 50 years of age as a booster dose to be given at least seven months following primary vaccination (the second dose) with VLA2001 (homologous booster dose) or with an adenoviral vector COVID-19 vaccine (heterologous booster dose).

On March 2, 2023, Valneva also provided an update on its pivotal Phase 3 Study COV-Compare (VLA2001-301). In this study, neutralizing antibodies on Day 208 (six months after the second dose of the primary vaccination with VLA2001) were non-inferior compared to the active comparator AZD1222, an adenoviral vector vaccine. The fold decline of neutralizing antibodies over six months after a second vaccination with VLA2001 was similar to the active comparator, and less pronounced than for other licensed COVID-19 vaccines. The T-cell response against the spike protein elicited upon vaccination with VLA2001 was in the same range as for the active comparator. Moreover, T-cell reactivity against the nucleocapsid and membrane protein was induced upon vaccination with VLA2001.

Additionally, results from VLA2001-304, a Phase 3 study in older adults, 56 years of age and above, showed that VLA2001 was well tolerated by these participants when administered as a two-dose or three-dose immunization, thus confirming the previously reported favorable safety profile of VLA2001. In this age group, a two-dose vaccination with VLA2001 was inferior in terms of geometric mean titers and seroconversion rates compared to younger adults aged 30 years and above. After two doses, immunogenicity in older adults was at a level which could be correlated with 60-70% vaccine efficacy against ancestral SARS-CoV-2. A third dose of VLA2001 further increased immunogenicity in participants aged 56 years and above to the titers associated with vaccine efficacy of >90% against ancestral SARS-CoV-2.

Finally, VLA2001's shelf life was recently extended to 21 months compared to 18 months previously. The Company will continue to submit data to further extend it.



VALNEVA SE – SUMMARY ON THE GROUP SITUATION

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2. BUSINESS DEVELOPMENT, RESULTS AND FINANCIAL POSITION OF THE COMPANY AND GROUP

See the translated excerpt of the Company's 2022 Universal Registration Document, on next pages.

We also refer you to the quarterly and half-year financial reports 2023, published on the Company's website www.valneva.com ("Investors" / "Financial Reports & Filings" / "Financial Reports" section), as well as to the press release relating thereto (in particular the press releases dated May 4, September 21, and November 9, 2023 - Please follow the "Media" / "Press Releases" section of the Company's website www.valneva.com).



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Other income, net of other expenses, reduced to €12.2 million in 2022 from €23.0 million in 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending and an increase of other expenses related to the provision for the ongoing Vivalis/Intercell merger litigation proceedings.

Valneva recorded an operating loss of €113.4 million in 2022 compared to an operating loss of €61.4 million in 2021, of which the COVID-19 program contributed a loss of €42.8 million in 2022 and a profit of €3.9 million in 2021. The other segments represented an operating loss of €70.6 million in 2022 compared to an operating loss of €65.3 million in 2021. Adjusted EBITDA (as defined below) loss in 2022 was €69.2 million compared to an adjusted EBITDA loss of €47.1 million in 2021.

Net result

In 2022, Valneva generated a net loss of €143.3 million compared to a net loss of €73.4 million in 2021.

Finance expense and currency effects in 2022 resulted in a net finance expense of €31.4 million, compared to a net finance expense of €8.6 million in 2021. This was mainly a result of a foreign exchange loss amounting to €12.6 million in 2022 primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions compared to a net foreign exchange gain of €8.1 million in 2021. Interest expenses net of interest income were €18.8 million in 2022 compared to €16.7 million in 2021.

Cash flow and liquidity

Net cash used in operating activities amounted to €245.3 million in 2022 compared to €76.9 million of cash generated by operating activities in 2021. Cash outflows in 2022 were mainly related to the operating loss generated in the period and non-cash revenues (cash received in previous periods), while during 2021 cash inflows mainly resulted from pre-payments received under the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €29.1 million in 2022 compared to €93.1 million in 2021, both mainly a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €215.1 million in 2022, which was mainly a result of proceeds from the equity subscription agreement with Pfizer, proceeds from a global offering as well as a draw-down of the credit facility provided by Deerfield Management Company & OrbiMed. Cash inflows in 2021 amounted to €154.5 million which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement in May as well as an additional global offering in November 2021.

Cash and cash equivalents were €289.4 million as at December 31, 2022, compared to €346.7 million as at December 31, 2021. This included €102.9 million of gross proceeds from an upsized global offering completed in October 2022, €90.5 (\$95) million from an equity investment by Pfizer completed in June 2022 as well as drawing of a total \$40 million from the Deerfield Management Company & OrbiMed loan agreement.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Valneva's current performance, performance trends, and financial condition.

Adjusted EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. Adjusted EBITDA is defined as earnings (loss) for the period before income tax, finance income/expense, foreign exchange gain/(loss), results from investments in associates, amortization, depreciation, and impairment.

A reconciliation of Adjusted EBITDA to net loss for the period, which is the most directly comparable IFRS measure, is set forth below:

(In € million)	12 months ended December 31	
	2022	2021
Loss for the period	(143.3)	(73.4)
Add:		
Income tax expense	(1.5)	3.4
Total finance income	(0.3)	(0.2)
Total finance expense	19.1	17.0
Foreign currency gain/(loss) - net	12.6	(8.1)
Result from investments in associates	—	—
Amortization	7.0	6.6
Depreciation	14.0	7.7
Impairment	23.2	—
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VALNEVA SE – SUMMARY ON THE GROUP SITUATION

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(b) Valneva SE (financial statements)

The Company's financial statements for the fiscal year 2022 were prepared in accordance with French generally accepted accounting principles as defined by the French accounting standards Committee (*Comité de la réglementation comptable*).

Operating income

Operating income amounted to €11.6 million at December 31, 2022, up from €6.2 million for the fiscal year 2021.

Revenues amounted to €5.8 million in 2022, compared to €3.6 million in 2021.

Other operating income (mainly licensing income) amounted to €3.1 million in 2022, compared to €2.4 million in 2021.

Operating Expenses

Operating expenses amounted to €37.7 million at December 31, 2022, compared to €36.9 million for the prior fiscal year.

Purchases of raw materials and external expenses amounted to €27.7 million in 2022, up from €26.4 million in 2021.

Employee benefits expense amounted to €8.1 million in 2022, compared to €7.4 million in 2021.

Amortization charges amounted to €0.9 million in 2022, compared to €2.3 million in 2021.

Income (loss) from ordinary activities

The operating loss from ordinary activities for the fiscal year 2022 was €-26.1 million, compared to €-30.8 million for the fiscal year 2021.

Net financial income/(expense)

Net financial income/(loss) amounted to €-1.6 million for the fiscal year 2022, compared to €+1 million for the fiscal year 2021.

Net exceptional items

Net exceptional result amounted to €-2.1 million for the fiscal year 2022, compared to €+0.3 million for the fiscal year 2021.

Corporate income tax

The negative 2022 income tax corresponds to a Research Tax Credit (*Crédit d'Impôt Recherche*) charge of €1.5 million and the income from the tax consolidation with Valneva France SAS for €0.2 million. The negative 2021 income tax corresponded to a Research Tax Credit charge of €1.8 million.

Net loss

Net loss for the fiscal year 2022 was €28.1 million, compared to €28.2 million in the prior fiscal year.

Fixed assets

Fixed assets fell from €164.6 million in 2021 to €164.3 million in 2022 (net value).

Total current assets

Current assets amounted to €324.9 million in 2022, compared with €191.7 million in 2021.

This increase is mainly due to the increase in cash position for €55 million and the increase in other receivables for €79 million, mainly related to the amounts recorded in current accounts with the various Group subsidiaries.

Equity

Shareholders' equity decreased from €307.2 million at December 31, 2021 to €468.9 million at December 31, 2022. A detailed description is provided in the Notes to the parent entity financial statements for the fiscal year 2022.

Liabilities

Total debt decreased by €28.9 million, from €42.3 million at December 31, 2021 to €13.4 million at December 31, 2022.

Operating payables fell by €3 million, from €7.9 million for the fiscal year 2021 to €4.9 million in 2022. The decrease is mainly due to employee-related liabilities and employer contributions on vested convertible preferred shares recorded at December 31, 2021.

Other debts fell by €25.9 million, from €30.6 million at December 31, 2021 to €4.6 million at December 31, 2022, corresponding to the drop in amounts recognized in current accounts with the various Group subsidiaries.

Cash

Total cash amounted to €195.2 million at December 31, 2022, compared to €140.6 million on the previous fiscal year.

Net cash provided by operating activities represented an outflow of €-135.2 million at December 31, 2022, compared to an outflow of €-40.6 million at December 31, 2021, reflecting:

- a €-24.6 million outflow in cash flows for the fiscal year 2022;
- a change in operating assets and liabilities for €-110.6 million.

The net cash generated from investment activities was €0.4 million in 2022 and was negligible in 2021.

The net cash generated from financing activities amounted to €+189.5 million in 2022, compared to €+165.2 million in 2021. It mainly stems from the two capital increases in June and October 2022, which were described in detail in the notes to the parent entity financial statements prepared for the fiscal year 2022.



VALNEVA SE – SUMMARY ON THE GROUP SITUATION

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Results (and other key aggregates) of the Company for the last five years

Nature of items	Year ended December 31				
	2018	2019	2020	2021	2022
I – CAPITAL AT THE END OF THE YEAR					
Share capital (in euros)	13,816,043	13,819,939	13,645,584	15,785,863	(20,755,122)
Number of ordinary shares(*)	90,917,048	90,923,298	90,950,048	105,190,223	138,346,968
Maximum number of shares to be created by conversion of bonds	0	0	0	0	0
II – OPERATIONS AND INCOME FOR THE YEAR (in euros)					
Revenue excluding tax and financial income	3,876,876	4,641,374	4,075,352	5,669,070	9,126,333
Profit/(loss) before income tax, employee profit-sharing and depreciation allowance and provisions	(18,567,302.98)	(28,166,330.72)	(13,764,375.19)	(27,668,325.07)	(25,272,600.01)
Tax on profit (income if negative)	(1,727,572)	(1,866,427)	(1,073,156)	(1,773,649)	(1,703,333)
Employee profit-sharing due for the year	—	—	—	—	—
Income after tax employee profit-sharing and depreciation allowance and provisions	(16,847,324)	(27,991,662)	(14,564,023)	(28,222,330)	(28,116,982)
Distributed income	—	—	—	—	—
III – EARNINGS PER SHARE (in euros)					
Income after tax and employee profit-sharing, but before depreciation allowances and provisions	(0.19)	(0.29)	(0.14)	(0.25)	(0.17)
Income after tax employee profit-sharing and depreciation allowance and provisions	(0.19)	(0.31)	(0.16)	(0.27)	(0.20)
Dividend per share (indicate if gross or net)	—	—	—	—	—
IV – PERSONNEL					
Average headcount for the period	49	48	42	46	50
Annual payroll (in euros)	3,946,840.33	3,682,931.40	3,396,356.44	3,716,165.23	5,009,335.18
Total of amounts paid for social benefits for the year (social security, social welfare programs, etc.) (in euros)	1,593,324.98	1,586,429.08	1,416,443.11	3,639,222.00	3,025,306.43

(*) The figures do not include the convertible preferred shares of the Company, for the total amount of 789 for the fiscal years 2017 and 2018, then increased to 20,514 for the fiscal years 2019 and 2020, increased again to 48,862 for 2021 and then reduced to 20,514 for the fiscal year 2022.