#### **SPINEWAY**

Limited company with capital of 182 109.90 euros Head office : 7 Allée du Moulin Berger, Bâtiment 7 69130 Ecully

484 163 985 RCS Lyon

(the "Company")

#### COMBINED GENERAL SHAREHOLDERS' MEETING OF APRIL 4th 2023

#### Management and Group Report of the Board of Directors

Ladies and Gentlemen shareholders,

In accordance with the law and the statutes, we have summoned you to a mixed general meeting to report to you on the situation and activity of our Company during the financial year closed on 31 December 2022, and to submit the social and consolidated corporate financial statements for said financial year, approved by the Board of Directors on February 9<sup>th</sup> 2023 and various resolutions which fall within the scope of the Extraordinary General Meeting of the shareholders.

We will give you all the details and any additional information concerning the documents and documents provided for by the regulations in force and which have been kept at your disposal within the legal deadlines.

You will then take notice:

- reports from your Statutory Auditors,

- the supplementary report of the Board of Directors on the motions for resolutions not related to the approval of the financial statements for the past financial year.

- the report of the Board of Directors on the corporate governance established in accordance with the provisions of Article L. 225-37 of the French Commercial Code, which includes, in particular, the list of all the mandates and functions exercised in any company by each of the corporate officers of the company, during the past fiscal year, and the summary table of the valid delegations granted by the General Meeting of Shareholders to the Board of Directors in the area of capital increases.

In addition, we inform you that the following information and reports are attached to this report, in accordance with Article R. 225-102 of the French Commercial Code, the table showing the results of the company over the past five financial years.

# I. ACTIVITY AND SITUATION OF THE GROUP

# A. <u>Scope of consolidation</u>

This is the Spineway Group's fifth consolidation exercise, (hereinafter the "**Group**").

The Group includes SPINEWAY, the parent company of the Group, its US subsidiary SPINEWAY USA Inc., which is wholly owned and fully consolidated, its French subsidiary Distimp fully owned and acquired on June 25<sup>th</sup>, 2021, and fully consolidated from the same date and its French subsidiary Spine Innovations fully owned and acquired on July 21<sup>st</sup>, 2022, and fully consolidated from the same date .

#### B. <u>Group activity during the year</u>

Spineway Group closes the 2022 financial year with a turnover of 7 432 K€ compared to 4 290 K€ at the end of December 2021.

Consolidated operating profit amount to – 3210 K€ as of December 31, 2022 compared to –1 409 K€ as of December 31, 2021

Current profit before tax is –3026 K€ as of December 31, 2022 compared to – 1 186 K€ at December 31, 2021

The Group's net income stands at – 3 137 K€ as of December 31, 2022 compared to -1 583 K€ as of December 31, 2021.

# C. Significant events at Group level during the year

• A dynamic year

Following the acquisitions of Distimp (2021) and especially Spine Innovations (2022), the Group has been able to strengthen its geographical positions, develop its presence on the French market in particular, and extend its premium ranges. Its Group turnover thus increased by 73% to reach 7.4 M $\in$ , or 10 M $\in$  pro forma 1 year, its highest level ever. Spineway's contribution is 4.4 M $\in$ , up +13%.

• Reinforcement of equity

The conversion of convertible or exchangeable bonds into new or existing ordinary shares over the period from January 2022 to September 15, 2022 generated a capital increase of 1 615 380 euros through the creation of 14 713 624 332 shares of 0.0001 euro and an issue premium of 1 128 637.60 euros.

On September 15, 2022, by decision of the Extraordinary General Meeting of July 25, 2022, Spineway reversed its shares by exchanging 1 new share with a nominal value of 4.00 euros for 40 000 old shares of 0.0001 euro nominal value.

Following this reverse stock split, Spineway carried out a capital reduction on September 19, 2022 resulting in the reduction of the legal nominal value of the share from 4.00 euros to 0.05 euro. At the end, the share capital amounted to 38 092 euros, made up of 761 848 ordinary shares.

From September 19 to December 31, 2022, the conversion of convertible or exchangeable bonds into new or existing ordinary shares generated a capital increase of 2 880 350 shares of 0.05 euros each and an issue premium of 1 755 982 euros.

The capital as of December 31, 2022 is 182,110 euros and is made up of 3,642,198 shares of 0.05 euro each.

• Group strategic growth plans

On July 21st, 2022, the Spineway Group announced the acquisition of 100% of the capital of the French company Spine Innovations, a company specializing in cervical and lumbar disc prostheses. The company has developed, in collaboration with renowned French surgeons, and after more than 10 years of Research & Development, the first viscoelastic lumbar prosthesis called "LP-ESP" which was implanted in 2004 at the University Hospital of La Pitié Salpetriere in Paris. Patented one-piece ESP viscoelastic (shock-absorbing core) disc prostheses allow surgeons to implant a device that mimics the movement and behavior of a natural disc. They are now used in more than 15 countries and Spine Innovations aims to become a key player in the field of disc prostheses worldwide thanks to this innovative technology.

Based in Lyon and Mulhouse, Spine Innovations relies on a team of 15 people and mainly markets its products in France, Europe and Australia. Over the 2020/2021 financial year, the company achieved a turnover of €4.2 million, of which 76% internationally. Positioned in a segment and territories complementary to those of Spineway, Spine Innovations offers numerous synergies to be developed.

In line with its growth strategy, this new acquisition allows Spineway to add a new segment to its product offering, strengthen its positions in France and internationally and expand its teams.

• IMS participation

Since Integral Medical Solutions (IMS) did not deploy the operational plan provided for when it acquired a stake in the Spineway Group, the latter had initiated proceedings before the Geneva Arbitral Tribunal, which rendered an award dated January 20, 2022 in in favor of Spineway, ordering them to pay the full purchase price of the shares, ie €4,160,000 plus interest, and to reimburse it for the arbitration costs incurred. IMS has never responded to the various ongoing procedures that are continuing as a result. To date, there is no indication of loss of value of IMS shares.

# D. Research and development activity

The Group is working on several innovation projects that it does not want to detail, for reasons of confidentiality, given the highly competitive market situation.

Research and development expenses amounted to 874 K€ in 2022 regarding those projects.

The research tax credit (CIR) amounts 223 K€ and the innovation tax credit amounts 3 K€ as of December 31, 2022.

Research tax credits and innovation tax credits have been classified as "Other income " for a total of 173 K€.

In the same way, the Group continues its intellectual property policy and regularly files patent and trademark applications.

#### E. Significant event since the end of the year

• IMS participation

The company has initiated the procedure for recognition of the decision of the Geneva Arbitral Tribunal in the United States, IMS's headquarters are in Delaware. IMS not having responded to the "petition", Spineway continued the proceedings in the US for IMS to be in default, prior to any collection process.

#### F. <u>Predictable evolution and future perspectives</u>

Spineway's business induces a significant need for working capital related to the collection delays of receivables, health facilities in France and distributors outside France, and a high level of inventory made necessary by the availability of implant ranges.

The 2023 continuity of business activity is based on:

- A cash level which raises 3.7 M€ at the closure,
- Assumptions of receipts related to the budget of turnover,
- The financing lines of the WCR given the banking pool. At the date of December 31st, 2022, a line of financial notes amounts 200 000 euros.

# II. ACTIVITY AND SITUATION OF THE COMPANY DURING THE FINANCIAL YEAR

# A. Situation and development of the company's activity during the year

# 1. Characteristics of the company and a reminder of the legal and financial operations carried out in previous years

Spineway is a public limited company that has been listed on the Euronext Growth market since 13 February 2013.

On December 14, 2017, Spineway obtained the visa of AMF No. 17-638 following the filing of the

Prospectus in order to transfer its shares to the "Offer to the public" compartment of the Euronext Growth market.

During the 2017, 2018, 2019, 2020 and 2021 financial years, it is recalled that the company consolidated its equity and quasi-equity through (i) the issue and exercise of the Ornane reserved for the benefit of the investment fund YA II PN, LTD, managed by Yorkville SPV Ltd, of (ii) the capital increase reserved for the company Tinavi Medical Technologies, (iii) the issue and exercise of the Oceane reserved for the benefit of the European fund High Growth Opportunities Securization Fund, of (iv) the issue and exercise of OCABSA for the benefit of Negma Group Ltd, of (v) the capital increase subscribed by the fund YA II PN, LTD and of (iv ) the capital increase for the benefit of Park Capital.

More specifically, during the past financial year, the following transactions were carried out:

- by decisions dated January 31, 2022, the Board of Directors, making use of the delegation of authority granted by the General Meeting of October 3, 2019 in its first resolution, noted the creation of 1,524,737,420 new ordinary shares and the correlative capital increase of €152,473.74, resulting from the conversion of OCA by Negma Group Ltd; as a result, the share capital was increased to €1,610,751.98;

- by decisions dated July 12, 2022, the Board of Directors, making use of the delegation of authority granted by the General Meeting of October 3, 2019 in its first resolution, noted the creation of 6,366,402,112 new ordinary shares and the correlative increase of €636,640.21, resulting from the conversion of OCA by Negma Group Ltd; as a result, the share capital was increased to €2,247,392.19;

- by decisions dated September 7, 2022, the Board of Directors, making use of the delegation of authority granted by the General Meeting of October 3, 2019 in its first resolution, noted the creation of 8,000,000,000 shares new ordinary shares and the correlative capital increase of €800,000, resulting from the conversion of OCA by Negma Group Ltd; as a result, the share capital was increased to €3,047,392.19;

- on the same day, the Board of Directors, making use of the delegation of authority granted by the General Meeting of May 18, 2022 in its first resolution, canceled 1,874 ordinary shares of the Company; as a result, the share capital was increased to €3,047,392.00.

In addition, as previously indicated, Spineway finalized on September 19, 2022 a reverse stock split of its shares by exchanging 1 new share with a nominal value of  $\leq 4.00$  for 40,000 old shares with a nominal value of  $\leq 0.0001$ . This transaction, carried out by decision of the company's shareholders meeting at an Extraordinary General Meeting on July 25, 2022, took effect on September 15, 2022.

The old Spineway shares with a par value of 0.0001 euro (ISIN code: FR00140072P8) were delisted from the Euronext Growth market after the market closed on September 14. They were replaced by new Spineway shares with a nominal value of €4.00 (ISIN code: FR001400BVK2) on September 15, 2022 and allocated on September 19, 2022. The mnemonic code (ALSPW) remained unchanged.

Finally, pursuant to decisions dated September 19, 2022, the Board of Directors:

- noted the finalization and the result of the operation to consolidate its shares by exchanging 1 new share with a nominal value of  $\leq 4.00$  for 40,000 old shares with a nominal value of  $\leq 0.0001$  and, consequently, the modification the number of shares making up the share capital from 30,473,920,000 ordinary shares to 761,848 ordinary shares; And

- decided to reduce the capital of the Company from 3,047,392 euros to 38,092.40 euros, representing a capital reduction of an amount of 3,009,299.60 euros by charging the losses of the Company (to the account "Carried forward again" in the amount of 2,038,532.60 euros and, the balance, i.e. the sum of

970,767.00 euros, by allocation within the item "Other reserves" sub-account of unavailable reserves to which may be charged, on decision of the General Meeting of the Company's shareholders and, to the extent, any loss for the financial year ended December 31, 2022) and reduction in the nominal value of the shares composing the Company's capital by 4.00 euro to 0.05 euro.

As a reminder, the bond loan taken out by the company Negma Group Ltd was settled on December 31, 2022.

As of December 31, 2022, the share capital (legal) therefore amounted to 38,092.40 euros, while the share capital (accounting), due to the effect of the regular conversion of OCAs by Negma Group Ltd, amounted to  $\leq$ 182,109.90.

# 2. Analysis of the company's activity during the past financial year

In 2022, the company achieved a turnover of 5 256 K€ compared to 4 272 K€ in 2021.

Operating profit amounted to -1 923 K€ compared to -1 089 K€ in 2021.

Current profit before tax amounted to -1 548 K€ compared to -827 K€ in 2021.

Finally, after an exceptional result of -436 K€, the financial year ended December 31, 2022 resulted in a net book loss of -1 758 K€ compared to -1 513 K€ in 2021.

# **<u>B.</u>** Significant events since the end of the year

• IMS participation

Since Integral Medical Solutions (IMS) did not deploy the operational plan provided for when it acquired a stake in the Spineway Group, the latter had initiated proceedings before the Geneva Arbitral Tribunal, which rendered an award dated January 20, 2022 in in favor of Spineway, ordering them to pay the full purchase price of the shares, ie  $\notin$ 4,160,000 plus interest, and to reimburse it for the arbitration costs incurred. IMS has never responded to the various ongoing procedures that are continuing as a result. To date, there is no indication of loss of value of IMS shares.

#### C. Research and development activity

Development expenses include direct and indirect costs incurred on projects and in particular the salaries of researchers, engineers, and technicians as well as subcontracting costs incurred for development activities.

The development effort gives rise, over the fiscal year, to the recognition of capitalized production of development costs in the "Intangible assets" account in progress for an amount of 874 K€ in 2022 compared to 572 K€ for 2021. When the costs are activated, they will be amortized on a straight-line basis.

In 2022, 588 K€ of R&D project costs so far in intangible assets in progress were put into service, compared to 249 K€ in 2021. They are amortized on a straight-line basis over five years. When there is

an indication of loss of value, and at each closing of the financial year, the development projects entered in the assets of the balance sheet are the subject of an analysis in order to ensure that each project still meets the criteria activation. If necessary, a depreciation is recognized.

In 2022, 19 K€ were exceptionally amortized and removed from fixed assets following project shutdowns.

As of December 31, 2022, total capitalized and commissioned R&D project costs amounted to 838 K€, amortized up to 100 K€.

#### D. Predictable evolution and future propects

Spineway will continue to lead the Group over the financial year by carrying out activities common to the Group, in particular research and development, marketing, logistics and, more broadly, all support functions. The Company is also continuing its international commercial development while working on synergies with its Distimp and Spine Innovations subsidiaries in order to address the entire market and as many territories as possible with more added value while securing its turnover. business and its historical customers.

#### E. Information about the payment terms of suppliers

Articles L.441-6-1 and D.441-4 of the French Commercial Code provide you with information concerning the payment terms of our suppliers and our customers. You will find them in appendix.

	Article D441 L1 - Factures reçues non réglées à la date de clôture de l'exercice dont le terme est échu					Article D441 L1 - Factures émises non réglées à la date de clôture de l'exercice dont le terme est échu						
	0 JOUR	1 0 30 JOURS	31 0 60 JOURS	61 0 90 JOURS	91 JOURS ET PLUS	TOTAL (1 JOUR ET PLUS)	0 JOUR	1 0 30 JOURS	31 0 60 JOURS	61 0 90 JOURS	91 JOURS ET PLUS	TOTAL (1 JOUR ET PLUS)
(A) Tranches de retard de paiement												
Nombre de factures concernées	19		>	$\langle$		57	4		>>	$\langle$		83
Montant total des factures concernées HT	49 537 €	74 564 €	21616€	199€	91 158 €	187 537 €	7051€	309 103 €	121 640 €	15 124 €	467 405 €	913 272 €
Pourcentage du montant total des achats HT de l'exercice	1%	2%	1%	0%	2%	5%						
Pourcentage du chiffre d'affaires HT de l'exercice			>>	$\langle$			0%	6%	2%	0%	9%	17%
	(B) Factures exclues du (A) relatives à des dettes et créances litigieuses ou non comptabilisées											
Nombre des factures exclues					-							
Nombre total des factures exclues						-						
© Délais de paiement de référence utilisés (contractuel ou délai légal - article L441-6 ou article L443-1 du code de commerce)												
Délais de paiement de référence utilisés pour le calcul des retards de paiements	60 jours date de facture - Sauf 1 fournisseur réglé par traite à 90 le 15 du mois				Délais contractuels propres à chaque client							

# **III. SUBSIDIARIES AND PARTICIPATIONS**

In 2022, the American subsidiary, Spineway USA Inc., generated sales of 4 KUSD. The result is a loss of \$ -107 KUSD.

In the 2022 financial year, the French subsidiary Distimp, 100% owned, generated revenue of 1 339 K $\in$ . The result for the year ended with a net accounting result of -867 K $\in$ .

In fiscal year 2022 (financial year from 01/10/21 to 31/12/22), the French subsidiary Spine Innovations, 100% owned, generated revenue of 4 896 K $\in$ . The result for the financial year shows a net accounting result of -2 072 K $\in$ . The contribution to the result of this entity since its acquisition date on July 21, 2022 is -699 K $\in$  for a contributed revenue of 1 740 K $\in$ .

# **IV. RESULTS - ASSIGNMENT**

#### A. <u>Review of accounts and results</u>

We will now present to you in detail the annual accounts that we submit for your approval and which have been drawn up in accordance with the rules of presentation and valuation methods provided for by the regulations in force.

As a preliminary point, we draw your attention to the fact that a change in the accounting estimate was made during the financial year: the amortization period for the instrument kits went from 3 years to 7 years from January 1, 2022, duration corresponding to the average duration of use of the instruments according to quality data and analyses.

During the fiscal year ended December 31<sup>st</sup>, 2022, revenue amounted to 5 256 163 euros compared to 4 272 425 euros for the previous fiscal year.

The amount of other operating income is 1 413 756 euros.

The amount of purchases and inventory changes amounted to 1 411 262 euros compared to 1 263 020 euros for the 2021 financial year.

The amount of other purchases and external charges amounts to 2 540 046 euros.

The amount of taxes and duties amounted to 133 470 euros compared to 72 815 euros for the previous year.

The amount of wages and salaries amounts to 2 741 085 euros and the amount of social charges amounts to 1 043 146 euros for an average salaried workforce amounting, at the end of the fiscal year, to 35 people.

The amount of depreciation and provisions is 511 112 euros.

Operating expenses for the financial year totaled 8 593 345 € compared to 6 279 524 € for financial year 2021.

The operating profit for the financial year was – 1 923 426 euros.

As for the current profit before tax, taking into account the financial result of 375 677 euros, stands at – 1 547 749 euros.

After taking into account:

- exceptional profit of – 435 575 euros,

- corporate tax of -225 773 euros,

the result for the year ended December 31<sup>st</sup>, 2022, shows a net accounting loss of -1 757 551 euros.

As of December 31<sup>st</sup>, 2022, the total balance sheet of the Company amounted to 27 484 543 euros compared to 25 247 996 euros for the 2021 financial year.

# B. <u>Allocation of income</u>

We kindly ask you to approve the financial statements (balance sheet, income statement and notes) as presented to you which show a net accounting loss of -1757550.95 euros which we also suggest that you allocate this entire loss the follow way :

-up to ...... – 970 767.00 euros, to the "Other unavailable reserves" sub-account, which would thus be increased from 970,767.00 euros to zero euros,

Given this allocation, the equity of the company would be 23 917 673 euros.

# C. <u>Previous dividend distributions</u>

In order to comply with the provisions of article 243 bis of the French General Tax Code, we remind you that no dividend has been paid in respect of the last three financial years.

#### D. Non tax deductible expenses

In accordance with the provisions of Articles 223 quater and 223 quinquies of the French General Tax Code, we ask you to approve the expenses not included in the tax deductible expenses, which amounted to 29 181 euros and which, taking into account the result fiscal deficit, have reduced the reportable deficit.

# E. <u>Analysis of the evolution of the results and the financial situation of the company</u>

As previously explained, the company saw its turnover increase from 4 272 K€ in 2021 to 5 256 K€ in 2022.

Borrowings and debts amounted to almost 3 314 K€ as of December 31<sup>st</sup>, 2022, compared to 3 868 K€ as of December 31<sup>st</sup>, 2021.

The "Cash" and "Marketable securities" items on December 31<sup>st</sup>, 2022, amounted to 3 657 K€ compared to 8 694 K€ at December 31, 2021.

# V. RISKS AND UNCERTAINTIES TO WHICH THE COMPANY IS CONFRONTED

The Group operates in a demanding, particularly regulated and constantly changing environment. This requires it to constantly take care to identify and control the risks whose occurrence would be likely to have an unfavorable effect for the Group, its activities, its financial situation, its results or the price of its title. This section presents the main risks to which the Group believes it is exposed.

The Group has carried out a review of the risks that could have a significant unfavorable effect on its activity, its financial situation, its results or its ability to achieve its objectives and considers that there are no other significant risks than those presented. below. Other risks of which the Group is not currently aware or which it does not consider significant at the date of this report could have a negative effect on its activity, its financial situation, its results or its ability to achieve its objectives.

A summary of these risks is presented in the table above.

The detailed description of the main risk factors likely to have a negative impact on the company, its activity, its financial situation, its results or its ability to achieve its objectives is appended to this report (Appendix 1).

Number	Risk	Probability of occurrence	Impact of the risk					
	1 - Financial risks							
1	A sharp improvement in the risk of dilution following the termination of the proven dilutive contract of 2.2% of the accounting share capital in the event of the exercise of all the dilutive instruments	Medium	Low					
2	A substantial liquidity risk increased by economic factors	Medium	Medium					
	2 - Risks related to external growth operations based or	n innovation						
3	A risk related to the implementation by Spineway of its growth strategy which could turn out to be slower or more difficult than expected	Medium	High					
	3 - Risks related to the activity and the market in which the Company operates							
5	Risks related to the competitive environment based on the characteristics of the market which could in particular penalize the gross margin	High	Medium					
	4 - Third parties risks							
6	Spineway's close dependence on its international distribution network	Medium	Medium					
7	A risk of dependence on production suppliers for specific supplies and processes	Medium	Medium					
	5 - Legal risks							
8	Increased risks related to regulatory constraints, particularly European ones	Medium	High					
9	Risks related to the protection and the necessary control by the Company of its intellectual property rights	Medium	Low					
10	The risks related to a possible questioning of the responsibility of the Company due to defective products reinforced by the sector of activity	Low	Medium					

#### VI. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT POLICY

As of December 31, 2022, the company's debt is mainly made up of short-term debt, which is made up of Mobilization of Receivables Born Abroad ("MCNE"). This short-term tool is indexed to the 3-month Euribor rate. MCNE are at variable rates.

The detail of the short-term tool used as of December 31, 2022 is as follows:

MCNE: 199 571 euros out of a total of 200 000 euros.

The contract concluded in October 2019 with Negma Group LTD by issuing OCAs with BSAs attached for a potential total amount of 40 million euros has enabled a cash contribution of 22.6 M€ since its conclusion. It expired in September 2022.

As of December 31, 2022, the Company recognized five outstanding bank loans, including four PGEs taken out in the context of COVID-19 for a total of €1 270 K€ over a minimum period of 12 months at a rate close to 0% with banking establishments partners.

As this health context has persisted, the company has opted to defer the start of repayment of these loans to one year. The PGEs began to be reimbursed in June 2022. The residual amount as of December 31, 2022 of the PGEs is 1 000 K€.

The other bank loan covers 10% of the remaining amounts due on December 31, 2022.

The BPI loans taken out in 2014 for 400 K€ and 600 K€ respectively were fully repaid on December 31, 2022.

#### VII. TABLES OF RESULTS FOR THE LAST FIVE YEARS

To this report is annexed, in accordance with the provisions of Article R. 225-102 of the French Commercial Code, the table showing the results of the company during the last five financial years closed by the company. (Appendix 2).

#### VIII. SHAREHOLDING

#### A. Main shareholders

The company is not aware of any natural and/or legal persons holding, as of December 31<sup>st</sup>, 2022, directly or indirectly, more than one-twentieth, one-tenth, three-twentieth, one-fifth, one-quarter, one-third, half, two-thirds or nineteen-twentieths of the capital or voting rights at general meetings, and whose identity should be mentioned in this report in accordance with the provisions of Article L. 233-13 of the Code of business.

#### B. <u>Auto-holding – Share Buyback program</u>

The treasury shares held as of December 31<sup>st</sup>, 2022, represent a total of 67 treasury shares, for a total of 70.35 euros.

Over the year, 3 327 754 shares were purchased, and 364 757 shares sold.

A liquidity contract was signed with Portzamparc Stock Exchange Company.

A share buyback program was authorized by the Shareholders' Meeting April 11<sup>th</sup>, 2022, in accordance with the provisions of Article L. 225-209 of the French Commercial Code and the General Regulation of the "Autorité des Marchés Financiers", in accordance with following:

Securities concerned: ordinary shares.

Mnemonic code / ISIN code: ALSPW / FR0011398874

Authorization of the transaction: Ordinary General Meeting of April 11, 2022 (6<sup>th</sup> resolution).

Maximum share of capital whose purchase was authorized by the General Meeting: 10% of the shares making up the share capital.

Maximum purchase price: one euro (1 €)

Objectives in order of priority:

- promote liquidity and facilitate the price of the Company's securities through an Investment Service Provider acting independently under a liquidity agreement in accordance with the Association's Code of Conduct French Financial Markets recognized by the Autorité des Marchés Financiers,
- cancel the shares thus redeemed by way of capital reduction, subject to the adoption by the General Meeting of shareholders, ruling on extraordinary matters, of a specific resolution relating to this capital reduction,
- allocate shares to employees or corporate officers of the company and to French or foreign companies or groups related to it in accordance with legal and regulatory conditions, in particular, as part of the participation in the fruits of the company's expansion employee share ownership plans or company savings plans, the stock option plan or by way of free allocation of shares or in any other condition permitted by the regulations,
- remit, within the limit of five percent (5%) of the share capital, the shares in payment or exchange, in particular, in the context of external growth operations,
- allot the shares upon the exercise of rights attached to transferable securities giving right by reimbursement, conversion, exchange, presentation of a warrant or in any other way, to existing shares of the company.

Redemption Method : Purchases, transfers or transfers may be made by any means, on one or more occasions, on or off the market, including block transactions (the maximum portion of the redemption program may be by way of acquisition or transfer of block of securities that can reach the totality of the authorized program.

Duration of the program: 18 months

#### IX. OPERATIONS OF OFFICERS AND PERSONS REFERRED TO IN ARTICLE L. 621-18-2 OF THE MONETARY AND FINANCIAL CODE ON THE SECURITIES OF THE COMPANY

In accordance with the provisions of Article L. 621-18-2 of the French Monetary and Financial Code and Article 223-26 of the AMF General Regulations, we remind you that shareholders must be informed of the transactions referred to in Article L. 621-18-2 which were carried out during the past financial year, by the persons referred to in that Article.

During the past financial year, no transaction referred to in Article L. 621-18-2 of the French Monetary and Financial Code was carried out.

# X. EMPLOYEE PARTICIPATION

In accordance with the provisions of Article L. 225-102 of the French Commercial Code, we hereby indicate the statement of employee profit-sharing on the last day of the financial year, ie December 31, 2022.

The proportion of capital represented by the shares held by employees as of December 31, 2022, as defined in Article L. 225-102 of the French Commercial Code, is nil.

# XI. ALLOCATION OF FREE SHARES AND STOCK OPTIONS

We refer you to the reports established elsewhere by the Board of Directors in accordance with the provisions of Articles L. 225-197-4 and L. 225-184 of the French Commercial Code.

# XII. AGREEMENTS REFERRED TO IN ARTICLES L. 225-38 AND FOLLOWING OF THE CODE DE COMMERCE

We ask you to take note of the fact that no new agreement falling within the scope of Article L. 225-38 of the Commercial Code has been entered into during the past financial year, and that the agreements entered into and authorized previously continued during the past financial year.

Your Statutory Auditors have been duly informed of this agreement which they have described in their special report.

# XIII. ADMINISTRATION AND CONTROL OF THE COMPANY

# A. Choice of the method of exercise of the general direction

In accordance with Article R. 225-102 of the French Commercial Code, we remind you that the Board of Directors, in its meeting of November 22, 2012, decided that the general management of the company is assumed by the Chairman of the Board of Directors. 'Administration.

# B. Status of the terms of office of the Directors and the Statutory Auditors

#### 1. Administrators' mandates

No term of office expires at this General Meeting.

#### 2. Statutory Auditors' mandates

No auditor's mandate will expire at this General Meeting

#### 3. Attendance fees

We propose to allocate an annual amount of up to four thousand euros (6 000  $\in$ ) in attendance fees in order to remunerate directors (independent) for the current and subsequent financial years, until a new decision by the General Meeting of Shareholders decides otherwise.

# C. Internal control procedures

The Company has put in place internal control provisions to ensure rigorous financial management and control of risks.

A description of the main existing provisions on internal control is presented below.

The Group's internal control system consists of a set of control mechanisms and external services set up by management to ensure the sound and efficient management of the company's business and assets.

# Accounting and financial information:

The accounting of the company is governed by the Commercial Code and, more generally, by the legal and regulatory environment, in accordance with the provisions of the General Accounting Plan.

In this context, and in addition to the mandatory documents, are established:

- weekly monitoring of banking positions and monthly forecasts.
- a weekly billing situation.
- a monthly statement of turnover and gross margin by customer and by range,
- a cash analysis carried out monthly including the review of receipts and customer outstandings
- monthly inventory reporting.

- monthly management financial statements in connection with the implementation of monthly accounting closings and the development of numerous management reports.

- the implementation of a company project management policy common to all departments.

- the implementation of quarterly budget monitoring (analysis of actual-budget variances) and a biannual reforecast process.

- the implementation of a sales and supply forecast policy including the collection of customer information and developed in consultation between the sales, supply and finance departments.

The financial function is managed internally by the Administrative and Financial Director. The accounting function is provided with the assistance of an external and independent public accountant (BBM Baker Tilly 4 rue Paul Valerien Perrin, 38 170 Seyssinet).

The realization of the payroll and the tax review are entrusted to this accountant.

Accounts prepared in accordance with French standards are produced with the assistance of the accounting firm and are submitted for audit to the Company's statutory auditors. The administrative and financial department reports to the Chief Executive Officer of the Company.

# D. Social and environmental consequences of the company's activity

The nature of the Group's activities does not pose a significant risk to the environment.

However, the Company is mindful of environmental and sustainable development issues and is developing a digital approach (priority area of the 2021 marketing plan).

Thus, Spineway is continuing its digital catalog project and the dematerialization of technical brochures as well as the deployment of a mobile and tablet application in order to reduce the printing of documentation. The constant evolution of products requires frequent updates. Similarly, the Company provides computerized models of its documentation to its distributors and offers them to print documentation locally, in order to reduce the energy costs related to the transport of documents. In addition, the Company has designed, in-house, a scalable and reusable stand structure (congresses, trade shows), which reduces waste linked to the destruction of single-use joinery (the most widespread practice). The reuse of an evolutionary structure also allows the Spineway stand to be given a new look, as its congress stands evolve, adding to the previous structure. Similarly, the company has rolled out electronic signature management throughout the group, enabling it to speed up the dematerialization project and limit all printing to a strict minimum. An electronic document management project is also underway across the entire group in 2023.

In order to coordinate all RSA actions, the Group has set up a CSE operational committee led by the Human Resources Manager. Similarly, the group is considering the creation of a CSR group within the Administration Committee.

Your Board invites you, after reading its supplementary report and the reports presented by your Statutory Auditors, to adopt the resolutions it submits to your vote.

Made in Ecully, 31<sup>st</sup> of January 2022

> **Board of Directors,** Stéphane LE ROUX

This report is available in both English and French. In case of discrepancy, the French version shall prevail.

#### **SPINEWAY**

Limited company with capital of 182 109.90 euros Head office : 7 Allée du Moulin Berger, Bâtiment 7 69130 Ecully

484 163 985 RCS Lyon

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#### COMBINED GENERAL SHAREHOLDERS' MEETING OF APRIL 4th 2023

Appendix to the management and group report

# Appendix 1

Risks and uncertainties facing the company

#### 1. Financial risks

1.1.1 A proven risk of dilution of 2.2% of the accounting share capital in the event of the exercise of all the dilutive instruments

The exercise of all the dilutive instruments issued on the date of this report would result in the issuance of new shares. These new shares could represent up to nearly 2.2% of Spineway's accounting share capital.

In September 2022, Spineway carried out a share consolidation which led to the issue of one new share for 40,000 old ones, bringing the share price and nominal value to  $4 \in$ . The company subsequently reduced the nominal value, bringing it down to  $0.05 \in$ .

The impact of the dilutive items listed below thus takes these new parameters into account.

Spineway has used until September 2022 dilutive financing tools consisting, at the date of this report, in:

# - the issue and exercise of ORNANE (Bonds Redeemable in Cash and New and Existing Shares) reserved for the benefit of the investment fund YA II PN Ltd, managed by Yorkville SPV Ltd (ORNANE Yorkville):

100 bonds were issued and converted.

267,379 BSA (share subscription warrants) were attached to these ORNANE, including:

. 129,574 BSAs were exercised; and,

. 137,805 BSA remain in circulation and give right to an equivalent number of shares.

# - the issue and exercise of OCEANEs (Convertible Bonds Exchangeable for New or Existing Shares reserved for the benefit of the European High Growth Opportunities Securization Fund (OCEANE ABO):

Of the 1 040 bonds (OC) issued, 1 039 OC were converted, and 1 OC matured without being converted (this OC was canceled during the 2020 financial year).

81 249 999 BSAs were attached to OCEANE ABOs, including:

. 333 333 BSAs were exercised and,

. 80 916 666 BSA remain in circulation. These warrants give the right to an equivalent number of shares. Post consolidation, these warrants represent a right to issue 2 026 shares.

<sup>&</sup>lt;sup>1</sup> The accounting share capital corresponds to the actual share capital, which may not have been fully endorsed legally (capital increases being legally recorded periodically and therefore grouped and not over time). At the closing date of 31/12/21, the legal share capital amounts to €1,458,278.24, divided into 14,582,782,342 shares with a par value of €0.0001 fully paid up and the share capital amounting to €1,576,029.77, divided into 15,760,297,542 shares with a par value of €0.0001 fully paid up.

# - the issue and exercise of OCABSA (bonds convertible into shares with stock warrants) for the benefit of Negma Group Ltd (OCABSA Negma):

11 199 OC were issued and converted (including 580 OC issued for commitment fees). The number of shares issued in conversion of convertible bonds cannot be anticipated since it depends on a ratio linked to market price assumptions. See paragraph 20.1 of the 2020 Universal Registration Document.

214 718 271 BSAs attached to OCABSAs were issued, representing a right to issue shares following the consolidation of 80 372 shares including:

. 1 607 359 136 (40,186 post consolidation) BSA held by Negma Group Ltd. These BSAs have not been exercised and give the right to an equivalent number of shares, i.e. post-consolidation 40 186 shares; And,

. 1 607 359 136 (40 186 post consolidation) BSA sold by Negma Group Ltd to Spineway and its management according to agreements dated January 6, 2021 and June 17, 2022.

The BSAs thus retroceded correspond to half of the BSAs issued on the occasion of the conversions of CBs drawn. The purpose of this acquisition of BSA is to enable the Company to leverage itself in the future and, to a lesser extent, to limit the risk of dilution.

These BSAs may therefore be either canceled or exercised as accretive instruments for the benefit of the Company and its management.

A summary table of the risk of dilution induced by all financial instruments is presented below.

No new allocation or additional issuance of financial instruments giving access to capital is planned as of the date of this report.

The Company is in fact looking for opportunities to diversify less dilutive financing with a clear desire to stop using this method of financing.

The dilution risk is based on current financing assumptions which may of course change given the implementation of Spineway's strategic plan.

The Company assigns this risk a **low** level.

The share capital mentioned in the table below and taken into account for the dilution calculations corresponds to the accounting capital of Spineway (and not to the legal share capital). The accounting share capital corresponds to the real share capital, which may not have been fully endorsed legally (capital increases being legally recorded periodically and therefore grouped and not over time). At the closing date of 12/31/22, the legal share capital amounted to  $38\ 092.40$  euros, divided into  $761\ 848$  shares with a par value of  $0.05 \in$  fully paid up and the accounting share capital amounts to  $182\ 109.90$  euros, divided into  $3\ 642\ 198$  shares with a par value of  $0.05 \in$  fully paid up and the accounting share capital amounts to  $182\ 109.90$  euros, divided into  $3\ 642\ 198$  shares with a par value of  $0.05 \in$  fully paid up.

Furthermore, the fully diluted information provided in the tables below implies that all of the dilutive instruments are exercisable (which depends on Spineway's future stock market prices).

Impact dilutif de l'exercice des instruments ouvrant droit à une	Instruments émis ou ayant vocation à être émis et ouvrant droit à une quote-part du capital social						
quote-part du capital social	BSA Spineway OCABSA Negma		BSA attachés aux OCEANE ABO	BSA attachés aux ORNANE Yorkville	Total		
dilutifs potentiels <sup>(1)</sup>	date des 06/01/21 et 17/06/22 à la société ou au	*Contrat fini en date du 18/09/22 * 40 186 BSA en tenant compte du ratio de regroupement de 1 nouvelle action pour 40 000 anciennes selon condition du regroupement de 09/22	2 026 BSA non exercées	exercées étant arrivé à	Au total post regroupement il reste 69898 BSA à exercer ayant une maturité entre 09/23 et 06/27		
Nombre d'actions nouvelles pouvant être créées du fait de l'exercice des instruments dilutifs émis à la date du document d'enregistrement universel	40 186	40 186	2 026	0	82 398		
Quote-part du capital social <sup>(3)</sup> (post émission du ou des instruments ciblés ouvrant droit à une quote-part du capital social) représentée par le nombre d'actions nouvelles créées	1,09%	1,09%	0,06%	0,00%	2,21%		
% de détention post-dilution d'un actionnaire détenant 1% du capital social de la Société (soit 36422 actions) à la date du document d'enregistrement universel	0,99%	0,99%	1,00%	1,00%	0,98%		
Nombre d'actions nouvelles fully diluted pouvant être créées selon une hypothèse d'utilisation de 100% des enveloppes de financement et du fait de l'exercice du montant total d'instruments non encore émis correspondant à ces tranches potentielles	40 186	40 186	2 026	0	82 398		
Quote-part du capital social <sup>(3)</sup> (post émission du ou des instruments ciblés ouvrant droit à une quote-part du capital social) représentée par le nombre d'actions nouvelles créées fully diluted	1,1%	1,1%	0,1%	0,0%	2,2%		
% de détention post-dilution fully diluted d'un actionnaire détenant 1% du capital social de la Société (soit 36422 actions) à la date du document d'enregistrement universel	0,99%	0,99%	1,00%	1,00%	0,97%		

(1) Dilutive instruments are understood as dilutive instruments issued on the date of the Universal Registration Document (BSA) and, according to the fully diluted approach, as the shares to be issued in the event of 100% use of the envelopes of financing signed to date (namely the lifting of all potential CBs and their 100% conversion) as well as additional related dilutive instruments (BSA). There is currently only

one category of potential dilutive instruments, namely the BSAs issued and not exercised on past CB issues (it being specified that these BSAs could not be exercised if their exercise price was not sufficiently interesting before their expiration date).

- (2) (2) See contract for the sale of BSA to Spineway by Negma Group Ltd dated January 6, 2021 referred to in paragraph 20.1 Financing agreement signed on October 18, 2019 with Negma Group Ltd » » of the Universal Registration Document 2020 and additional agreement post Universal Registration Document dated June 17, 2022.
- (3) (3) The accounting share capital corresponds to the accounting share capital at the closing date on 12/31/22, this being legally recorded periodically only given the significant number and frequency of conversions when tranches are exercised.

#### 1.2 A substantial liquidity risk increased by economic factors

The Company still needs significant financing given, on the one hand, high operating costs, particularly in connection with costly regulatory issues and significant working capital requirements, and, on the other hand, development projects. coming.

The Group's working capital requirements are impacted by:

- the need to have a large level of stock in connection with:
  - a depth of ranges and the need to offer sterile and non-sterile products,
  - the essential stocks on deposit and on consignment in hospitals (these stocks are intended to allow hospitals to have stocks available at all times to secure the performance of operations),
  - the management of separate references linked to approval dates and customer requirements in terms of very short supply times due to lack of anticipation on their part (orders placed are generally to be honored in less than 15 days);
- long customer payment terms (particularly in the context of its export markets outside Europe). These customer payment deadlines have a direct impact on Spineway's cash flow and can significantly lengthen the lag between the disbursements required for purchases and the receipt of revenue (this period can reach 6/8 months).
- the risk of customer default, particularly in view of the significant activity carried out in Latin America and the recurrent geopolitical and economic hazards in this zone, even though the proportion of turnover generated in this zone tends to fall with the development, particularly in France. The shortfalls in cash related to this subject are, however, low on the basis of payment defaults in recent years and taking into account the fact that all new customers are now subject to more restrictive payment conditions validated by contract;
- the impact of a potential unfavorable change in reimbursement policies for medical devices corresponding to a worldwide trend and thus present in all the markets addressed by Spineway due to the efforts of governments and other third-party payers aimed at containing healthcare costs by limiting both the coverage and the reimbursement rate applicable to new therapeutic developments. The adoption of these proposals or reforms could have a direct impact on cash requirements, which could impact sales mainly in Europe and the United States. In the short term, these sales are not significant, but the development of sales in these areas is integrated into Spineway's strategy, especially since current margin rates are higher there than in other areas. Such a development would require finding levers to save production costs, a more complex situation for Spineway due to the significant use of subcontracting and therefore potentially requiring investment needs before regaining sufficient margin levels; And,
- the recovery of activity and the growth in turnover linked to the integration in July 2022 of Spine Innovations (entity wholly owned) (responsiveness to customer needs). Eager not to lose market share, the Company is effectively anticipating short-term stock rebuilding needs, especially as its distributors have limited their stock coverage in order to absorb the effects of the Covid-19 crisis.

The financing of the Company was mainly carried out by strengthening its equity through capital increases, but also by bank debt in connection with government support measures.

For this, the Company subscribed from 2020 to four PGE (Loan guaranteed by the State) for a total amount of 1 270 K€ over 12 months at the rate of 0% with three historical partner establishments and a new banking partner, loans for which the Company has begun to repay.

In addition, the Company has used dilutive instruments issued in the context of financing provided by equity line type funds whose purpose is not to remain long-term shareholders. As such, the Company has continued until June 2022 the financing contract (bond loan with a maximum potential nominal amount of 40 M€) signed in October 2019 with Negma Group Ltd (OCABSA issuance contract). As such, Spineway launched 8 CB subscription tranches between the end of 2019 and June 2022 (for a total amount of 22 588 K€ by contribution in cash, including 4 000 K€ paid in 2022, 13 200 K€ paid in 2021, 3 388 K€ paid in 2020 and 2 000 K€ in 2019) and managed to keep this funding in place despite the health crisis and the difficulties of the financial markets.

Spineway makes a precise and regular update on its cash position (at least once a month) and has set up short-term and medium-term cash forecasting tools as well as monthly budget monitoring in order to gain in agility and responsiveness to this issue. The company has also set up cash forecasting tools based on its 5-year business plan in order to better identify possible financing given its needs.

As of December 31, 2022, the Group's cash flow thanks to all of these measures reached 5 525 K€.

Repayment maturities of less than one year mainly correspond to PGEs as well as to financial notes and mobilizations of claims originating abroad which, in practice, are renewed as and when the company needs them.

Debt statements	Gross amount	Under 1 year	Between 1 and 5 years	Over 5 years	
Loans	1 185	567	618		
Accrued interest is loans	7	7			
Bond issue	-	-			
Overdrafts - bank	-	-			
promissory notes	-	-			
Factoring of receivables abroad	200	200			
COFACE guarantee	-10	-10			
Financial lease debts	49	8	32	8	
TOTAL	1 431	774	650	8	

Schedule of financial debts as of December 31, 2022:

Certain borrowings taken out include non-financial bank covenants which were complied with as of December 31, 2022. The company does not anticipate, at 12 months, any non-compliance with covenants.

Business continuity 2023 is based on:

- collection assumptions linked to the turnover and operating expenditure budget, WCR financing lines granted by the banking pool.
- The current lines of financing revised sharply downwards in 2021 following the implementation of the PGE but which will be renegotiated again following the closing of the annual accounts according to an annual process in line with the strategic development axes and the progress of ongoing projects;

- Spineway anticipates maintaining the confidence of its main banking partners and more particularly of new players. In this context, Spineway does not anticipate any break in these relationships.

Spineway had secured its current cash needs and the financing of any development projects for the coming months thanks to the Negma Group Ltd financing envelope.

The Company assigns liquidity risk a **medium** level.

#### 2. <u>Risks related to external growth operations</u>

A risk related to the implementation by Spineway of its growth strategy which could turn out to be slower or more difficult than expected

Spineway wishes to carry out growth operations based on innovation and the migration of these ranges to more Premium ranges and on more mature markets with high added value in order to position itself as a European spine platform. These projects can be of several types and will facilitate the return to profitability by making it possible to reach a critical size which will make it possible to achieve synergies in turnover and cost savings.

On July 21, 2022, the Spineway Group acquired 100% of the capital of Spine Innovations, which has a range of non-fusion products with spinal prostheses (cervical and lumbar) and which has strong development potential in the competitive context. current situation, particularly on the European market and on markets with high added value (Australia, United States, etc.). This acquisition, which follows that of Distimp in June 2021, offers new growth prospects and significant long-term synergies. However, these expected revenue synergies could be slower than expected and the cost synergies less significant than expected.

This operation was financed in cash and saw the integration within the Group of the manager with solid marketing and operational experience in the spine as well as that of a quality team complementary to the workforce of the Spineway group.

The integration of men could pose difficulties. Spineway pays particular attention to the complementarity of people and makes every effort to secure not only its operational aspect but also, and more upstream, the support of people in the project.

Commercial development projects also based on innovation could be slowed down in the face of the current difficulties and regulatory context. Indeed, the Company is also working on other projects, in particular actions promoting organic growth, product innovation and the conclusion of commercial partnerships.

The Company makes every effort to ensure that these projects are accelerators of growth and a return to profitability by the integrated achievement of a critical size.

The Company assigns external growth risk a **medium** level.

# 3. <u>Risks relating to the activity and the market in which the Company operates</u>

Risks related to the competitive environment based on the characteristics of the market

The market for products related to spinal surgery is competitive and dominated by major American players (notably: Medtronic, Johnson & Johnson, Stryker or Zimmer) which cover between 60 and 80% of the global spinal implant market (source: Spineway).

These leading companies are solidly established and have considerable resources, far superior to those of Spineway.

Alongside these leaders, there are historically medium-sized players who can directly compete with Spineway products. A number of competitors focus on a specific product or part of the market, potentially making it more difficult for the Company to improve its overall competitive position in the market.

Furthermore, the innovation demonstrated by competing companies (development of less expensive and/or more efficient and/or higher quality technologies or products, or faster time to market than Spineway products) could affect the future growth of spineway. However, the new regulatory requirements restrict the possibilities for major innovation, particularly in terms of implants. Given these significant barriers to entry, many players are developing through external growth by targeting companies with innovative technologies or market shares worthy of interest.

Under these conditions, Spineway estimates:

- that competition continues to intensify but also offers opportunities for access to markets / products neglected by the major players who are also forced to rationalize their cost structure, particularly in the face of regulatory issues;
- that the phenomenon of concentration on a specific product or part of the market which characterizes the market will thus also be reinforced;
- that competition could lead to a drop in the price of its products, a reduction in its profit margins, and could therefore affect its ability to invest and develop its business.

A player on a human scale, Spineway has, faced with this competition, deployed a new marketing plan, as well as a new commercial policy and:

- now emphasizes a dual positioning of its product ranges: Premium for mature markets and highpotential customers, and Gold standard in markets for which Premium may remain inaccessible; thus, Spineway stands out and responds to a desire to have top-of-the-range products expressed by many countries/regions of the globe (in particular: Japan, United States and Europe), while maintaining its anchorage in territories with very varied economic situations;
- can now address, following the acquisition of Spine Innovations, all therapeutic indications by offering both fusion and non-fusion products;
- relies on the creation of a stronger partnership with customers and surgeons thanks to better listening and the consolidation of its presence in the field; a medical education and scientific service was thus set up in 2022 in order to strengthen this link and provide real support that benefits all parties;
- constantly seeks to develop innovative technologies, new products, to improve its existing products and to complete its ranges; several developments are also underway, according to a schedule defined by the Company for at least the next three years;
- has initiated an action plan aimed at strengthening its links with the referring surgeons on its markets via targeted actions and partnerships as well as by setting up a scientific council;

- ; conducts projects aimed at creating value and guaranteeing its market share via, in particular, product/innovation partnerships. Despite the deployment of this new commercial, marketing and scientific policy, increased competition could significantly affect the marketing by the Group of its products and in particular of its new innovative products. Indeed, the lengthy development, manufacturing and marketing process does not fully guarantee efficacy, acceptance by surgeons or obtaining approvals from regulatory authorities (regulatory bodies issuing sales authorization certificates ) and the paying bodies (social security or equivalent bodies for the reimbursement of medical expenses) despite the tests carried out upstream. The additional delays in the event of rejection of the first application for approval of new products are dependent on the points raised (minor or major) and may result in several months before approval, leaving more time for the competition to position itself.

#### 1.3.2 Risks related to the competitive environment based on market characteristics

The market for products related to spinal surgery is competitive and dominated by major American players (in particular: Medtronic, Johnson & Johnson, Stryker or Zimmer) which cover between 60 and 80% of the global spinal implant market (source: Spineway).

These leading companies are solidly established and have considerable resources, far superior to those of Spineway.

Alongside these leaders, there are historically medium-sized players who can directly compete with Spineway products. A number of competitors focus on a specific product or part of the market, potentially making it more difficult for the Company to improve its overall competitive position in the market.

Furthermore, the innovation demonstrated by competing companies (development of less expensive and/or more efficient and/or higher quality technologies or products, or faster time to market than Spineway products) could affect the future growth of spineway. The new regulatory requirements, however, restrict the possibilities of major innovation, particularly in terms of implants. Given these significant barriers to entry, many players are developing through external growth by targeting companies with innovative technologies or market worthy of interest.

Under these conditions, Spineway estimates:

- that competition will further intensify;

- that the phenomenon of concentration on a specific product or part of the market which characterizes the market will also increase;

- that competition could lead to a drop in the price of its products, a reduction in its profit margins, and could therefore affect its ability to invest and develop its business.

A player on a human scale, Spineway has, faced with this competition, deployed a new marketing plan as well as a new commercial policy and:

- now emphasizes a dual positioning of its product ranges: Premium for mature markets and high-potential customers, and Gold standard in markets for which Premium may remain inaccessible. Thus,

- conducts projects aimed at creating value and guaranteeing its market share via, in particular, product/innovation partnerships.

Despite the deployment of this new commercial, marketing and scientific policy, increased competition could significantly affect the marketing by the Group of its products and in particular of its new innovative products. Indeed, the lengthy development, manufacturing and marketing process does not fully guarantee efficacy, acceptance by surgeons or obtaining approvals from regulatory authorities (regulatory bodies issuing sales authorization certificates ) and the paying bodies (social security or equivalent bodies for the reimbursement of medical expenses) despite the tests carried out upstream. The additional delays in the event of rejection of the first application for approval of new products are dependent on the points raised (minor or major) and may result in several months before approval, leaving more time for the competition to position itself. The shortfall in terms of turnover depends on the market prospects specific to each product, countries in which delays in approval or reimbursement could occur. The competitive risk on innovations is however mitigated insofar as the new regulatory requirements restrict the possibilities for all players of major innovations, particularly in terms of implants, insofar as Spineway, like its competitors, must first integrate in its process of validating new constraints, particularly clinical ones, which slow down the obtaining of authorisations. Compliance with these new, more demanding regulations therefore penalizes the release of innovations (more complex and longer process) for all players. More generally, competition could thus harm the activities, results, financial situation, development and prospects of the Group.

The Company assigns this risk a **<u>high</u>** level.

# 4. <u>Risks related to third parties</u>

#### 4.1 Spineway's close dependence on its international distribution network

Abroad (74% of consolidated revenue as of December 31, 2022), Spineway distributes its products almost exclusively through independent distributors (indirect sales).

As of December 31, 2022, the weight of the main customers in the Group's consolidated revenue was quantified as follows:

- Spineway's main customer (distributor): 12% of consolidated revenue;
- the top 5 customers: 38% of consolidated revenue;
- the top 10 customers: 54% of consolidated revenue.

Spineway has in fact set up an indirect sales network through distribution agreements entered into with local distributors mainly located abroad without a full guarantee of real power of control. Such a distribution network therefore presents a major risk for the Company but guarantees that it can be established throughout the world. This risk has, for example, already been experienced during the liquidation in 2018 of the Company's main distributor on the American market, which led to a loss of turnover of more than 2 M€, the need to rebuild relations on American soil and setting up a new distribution network (which takes several years). This process of rebuilding market share in the United States is still in progress as of the date of this report.

This indirect sales network has its own constraints linked to its international and heterogeneous nature, and in particular:

- the existence of more or less restrictive and multiplied laws and regulations applicable to the products and services offered by the Group;
- possibilities of unanticipated changes in the laws or market conditions of these countries (the unfavorable development of reimbursement policies for medical devices corresponds to a global trend);
- limited protection in terms of intellectual property in certain countries;
- political and/or economic instability in certain countries in which the Group operates (particularly in Latin America);
- greater exposure in certain territories to financial risks.

Regarding this specific constraint, Spineway prioritizes its actions according to 4 main criteria:

- optimization of its product ranges, in particular in connection with the acquisition of the Distimp ranges and the penetration of the non-merger market with the acquisition of Spine Innovations, in order to improve the adequacy of its offer to customer expectations;
- improvement in the quality of instrumentation kits in line with the policy of migration to the Premium segment;
- prospection of markets with higher added value (Europe, Japan, Australia, United States).
- In connection with the development of sales in France, the risk of dependence on international sales will decrease accordingly, which has already resulted in 2022 in a reduction in dependence on distributors.

The success of the international marketing of Spineway products is therefore closely linked to its ability to forge links with its distributors and to retain them, but also to their financial health, expertise and ability to secure and develop their own clientele. Financial difficulties, non-payment and disagreements that could arise with these distributors or one of them would have an adverse effect on the Group. The occurrence of payment defaults generally follows a termination of contractual relations with a distributor, but may also result from endogenous factors specific to the distributor (financial situation) or even from the economic, geopolitical or regulatory context of the country.

Also, Spineway cannot guarantee that it will be able to retain these distributors or that they will continue to devote the resources necessary for the commercial success of its products, success which depends in particular on the marketing efforts and customer service deployed by the distributors.

In general, this indirect sales system places Spineway in a situation of commercial dependence with regard to the partners on which it relies, a dependence which will decrease further with the integration of Spine Innovations, which has significant access to the market. French and with the development of the Distimp ranges anticipated in this same market.

In order to limit this risk, the Company :

- is working on action plans aimed at securing its main historical customers, in particular through a new commercial policy and better marketing and scientific support;

- makes special efforts to develop the client portfolio so as to dilute the risk of dependency; is constantly looking for new distributors both in its historical areas and in new territories with a more favorable geopolitical and economic situation, despite distributor synergies with Spine Innovations which could strengthen the weight of certain individual customers;
- implements individualized financial support solutions in collaboration with organizations that will secure outstandings. The Group pays particular attention to these financial issues when signing new contracts and has reviewed its financing policy for instrumentation kits accordingly;
- works on the regulatory autonomy of privileged export territories so as not to depend on distributors in terms of approval.

Despite these measures, this situation of the Group's dependence on distributors and/or the potential deterioration in payment terms, or even the failure of distributors, could have consequences that would significantly affect business depending on the customer(s) concerned, the Group's results, financial situation, development and short-term outlook.

Nevertheless, the growth in sales in France (26% of consolidated turnover as of December 31, 2022 compared to 17% in 2021 testifying to the initiation of the strategic reinforcement plan in this territory), carried out directly with healthcare establishments (direct sale) but which can also be carried out through distributors within the framework of privileged partnerships or by using commercial agents having privileged links with the end customers (hospitals) of Spineway, makes it possible to limit this risk.

The Company assigns this risk a **medium** level.

# 4.2 A risk of dependence on production suppliers for specific supplies and processes

For the manufacture of its products, the Spineway group needs to source materials and, in particular, PEEK. With regard to this specific supply, the Company relies on a main supplier. Similarly, the Spineway group depends on 2 main subcontractors for the manufacture of its products (implants).

Spineway has nevertheless set up a process of referencing and quality approval of several suppliers in order to temporize this risk but considers that the postponement of production in the event of failure of a preferred supplier, in particular of PEEK raw material, to a secondary supplier could involve implementation delays leading to short-term supply delays while secondary suppliers organize themselves to absorb additional volumes. This risk is also mitigated by the desire to diversify products, in particular towards titanium products, which will reduce the share of dependence on one material and one supplier and will make it possible to have new alternatives of approved suppliers of quality and CE certified. Similarly, rationalization of instrument suppliers with a pool of reference suppliers in this field makes it possible to gain in profitability and dilutes the risk of dependence while increasing control of these vital supplies.

A project to internalize the production of the Spine Innovations ranges is also being deployed, which will significantly reduce this risk.

The Company assigns this risk a **medium** level.

# 5. Legal risks

#### 5.1 Increased risks related to regulatory constraints, particularly European ones

The process of obtaining and maintaining the approvals, legal and regulatory authorizations as well as the certifications necessary for the marketing of medical devices can be long depending on the country in question. In addition, there is no guarantee that these authorizations, if granted, will be consistent with commercial development plans. If Spineway does not obtain authorizations or certifications (in particular CE, FDA - Food & Drug Administration - or equivalent marking) for its future products or improvements made to its existing products, it could be prohibited, until it obtains them. , the marketing of its products in its various markets. The same would apply if the Company were to lose the authorizations or certifications it holds. These regulatory obligations and processes are valid in most of the countries in which Spineway markets or plans to market its products, with sometimes different constraints. Depending on the nature of the agreements, these obligations are either directly the responsibility of Spineway or the responsibility of its local distributor who may, if necessary, hold the approvals in its territory.

Rejections or delays in the certification process would necessarily involve forcing the Company to carry out costly additional tests and having to collect additional clinical data, which is often long and tedious to obtain. This could have a negative impact on the Company's financial results, on its competitive position and on its ability to market its products in the countries concerned.

Changes in regulations or standards applicable in one of the countries where Spineway operates may likewise, where applicable, affect the development of its products or cause the withdrawal or suspension of marketing authorizations, it being noted that the Company has never been confronted with a problem of non-conformity of its products.

Indeed, the global regulatory context is constantly changing and tends to reinforce its constraints (evolution of techniques and harmonization of legislation throughout the world). Spineway has ensured that it has the appropriate means for effective regulatory monitoring, in France and internationally, in order to anticipate changes:

- member of SNITEM;
- network of international consultants (formerly RADAR review published by Emergo);
- dedicated staff (quality monitoring and regulatory affairs);
- information sent by US FDA to registered companies.

Given the issues related to marketing certificates, Spineway constantly monitors the evolution of regulatory and legislative constraints in the areas in which it markets its products. Similarly, Spineway carefully studies the existing regulatory and legislative constraints in the countries it plans to market its products before initiating any commercial approach.

The Company has put in place an organization and support enabling it to address the specific risk arising from the evolution of the European regulatory environment: European Regulation 2017/745 relating to Medical Devices (hereinafter "MDR") in force since May 25, 2017 which specifies the basic provisions of the legislation applicable to the countries of the European community and in particular the essential requirements in terms of safety as well as the methods of conformity assessment. Its application results in the affixing of the CE Marking, more complete labeling (the labeling must include in particular: batch or serial number of the product, warnings, name of a European representative for manufacturers outside the EU, etc.). In addition, a review by a third-party body, called a notified body, is imperative and results in the issuance of a CE certificate. This RMD will only come into full effect from May 2024 with a relaxation by 2027 under certain conditions, following a first postponement and recent amendments in order to

allow manufacturers, authorities and notified bodies to adapt this new CE standard requiring a cumbersome and costly approval process.

By this date, product certifications under RMD are possible but not mandatory. Indeed, it is possible to continue marketing until the end of the certificate under the current MDD standard, namely in the case of Spineway in theory until May 2024 thanks to obtaining a period of validity of the current CE certificates. Spineway has thus secured its current product portfolio until 2025 (possibility of sale one year after the end of the MDD certificate) while initiating the registration process in accordance with the new regulatory requirements. Thus, reusable surgical instruments are certified in RMD and the Company has begun to file implant files according to a schedule taking into account the time required for the notified body to study the corresponding technical files.

Aware of this issue, Spineway has therefore anticipated this subject and mobilized significant budgets for 3 years, efforts which will continue over the coming period and at least until 2024, particularly given the significant clinical issues. . Clinical studies will have to be maintained over the full lifetime of the products and will induce significant maintenance investments beyond the date of RMD approval.

The Company can rely on a structured, competent team and be reinforced with the constitution of an internal clinical team to limit the risk of loss of authorizations, certifications or non-renewal.

In addition, Spineway's quality system enabled it to obtain ISO 13485 certification in 2006. Since 2006, ISO certification has been constantly renewed. Ongoing work to rationalize quality management at group level following the integration of Distimp and then Spine Innovations should eventually reduce some of the efforts at Group level in this area.

The Company assigns this risk a **<u>high</u>** level.

#### 5.2 Risks related to the protection and necessary control by the Company of its intellectual property rights

The Group favors an active policy aimed at protecting the exclusive nature of its intellectual property. However, the Group may not be able to maintain or obtain adequate protection and, therefore, retain all the resulting technological and competitive advantages.

The Group's success depends in part on its ability to protect its own processes and products against the illicit uses that could be made of them by third parties. To protect its rights, Spineway relies on the protection offered by patents, trademarks, trade secrets, know-how, confidentiality agreements and other contractual restrictions. However, these means only offer limited protection and may not prevent unlawful use of the rights, products and technologies belonging to the Company. Unauthorized use of the Company's processes or products by third parties could in particular lead to the Company losing a competitive advantage or market share, as well as an inability to conquer new market shares. Such events could have an adverse effect on the Group's business, assets or financial situation.

Conversely, the Company cannot guarantee that it will not infringe the intellectual property of others, for two main reasons:

- the number and complexity of existing international patents make it difficult to understand the real freedom to operate of the many devices already on the market.

- the impossibility of knowing in advance the patents being applied for and not yet made public, which could interfere, when published, with all or part of the Company's products or rights.

By controlling its R&D, by carrying out its own research, by commissioning an Intellectual Property firm to ensure monitoring, and by having its R&D carried out mainly in-house or in collaboration with referring surgeons supported by contracts including precise clauses relating to the intellectual property, the Company is strengthening its control of its intellectual property rights. The arrival of a scientific director and the reconstitution of a dedicated team thus allows better control of this subject.

#### On the ownership of rights

Any discovery made by an employee belongs to the employer. The employment contracts signed by Spineway with its employees nevertheless provide for the payment to the employees concerned of an inventiveness bonus.

In the event of filing, by Spineway, of patent(s) co-developed with surgeons (in the context of scientific and/or technological cooperation), a contract is signed and provides for the payment of royalties calculated on the basis of gross sales. These patents co-developed with the surgeons are the property of Spineway (the contracts include a waiver by the surgeons of intellectual property rights).

However, and in the event of persistent disagreement between the partners on the ownership of rights, there is a risk that the partner concerned will claim the intellectual property rights on the results to which it has contributed and may prevent or hinder the Company in the exploitation of the technology developed under these agreements. This is why Spineway has also set up a new procedure aimed at formalizing, in parallel with the payment of royalties, the transfer to Spineway of all the intellectual property rights of the co-developers attached to the patents filed by spineway.

#### <u>On patents</u>

Spineway holds several patents.

The advisability of filing patents abroad is measured according to the degree of inventiveness of said patent and the ability of the Company to act against possible infringers. Legislative disparities between countries could prevent the Company from adequately protecting its products, in one or more countries, or from ensuring an equivalent level of protection in the different countries.

Moreover, even when patents are filed abroad, the means and knowledge available to the Company do not allow it, in any event, to act systematically against offenders in the event of infringement. Spineway also believes that the risk of counterfeiting is real, and that this risk is reinforced with its development on the Asian markets and in countries that are more focused on *Gold Standard*.

In addition, the means and knowledge available to the Company do not allow it, in an exhaustive manner, to verify that a technique marketed is not itself infringing with regard to a registered patent or rights held by a third party. in a given territory and could see its liability sought and/or engaged in this respect. Any dispute could result in a judgment or decision unfavorable to the Company being rendered, which could affect its ability to protect its products. However, even if such a dispute had an outcome favorable to the Company, the fact remains that involvement in an administrative, legal or arbitration procedure of this type could be time-consuming and incur substantial costs for the Company.

#### On the know-how

The products developed by the Company also implement know-how.

The Company cannot guarantee that Spineway and its products, which are closely linked to its knowhow and trade secrets, are adequately protected against competitors and cannot be usurped or circumvented by them.

The Group seeks to limit the communication of key elements of its know-how (in particular in terms of R&D), to third parties, to the only information strictly necessary for the collaboration that it maintains with them and it contractually ensures that these third parties undertake not to divert, use or communicate this information, in particular by means of confidentiality clauses. However, the Group cannot guarantee that these third parties or that former employees respect these agreements, that the Group will be informed of a violation of these clauses, or that the compensation that it could possibly obtain would be sufficient with regard to the damage suffered.

#### <u>About brands</u>

The Company holds several trademarks, both European and registered in different countries of the world on all continents. Here again, the material means available to the Company limit its field of action in the event of possible infringement.

Indeed, third parties could still use or attempt to use this brand or other brands of the Group.

Similarly, if a third party were to use an identical or similar mark in the classes referred to in the registration certificates, any qualification of infringement could be held in check if the mark were considered to be invalid in that it is insufficiently distinctive and/or too descriptive in relation to the products it identifies.

If this risk were to materialize, it could compromise the protection of the names allowing the identification of the Company's products by customers, prospects and, in general, the public.

# Infringement actions

It is important, for the success of its business, that the Group be able to freely exploit its products and technology.

Despite its efforts, the Company cannot fully guarantee that there are no patents or other intellectual property rights of third parties likely to cover certain activities, products or technologies of the Group allowing these third parties to act for infringement, or on a similar basis, against the Group with a view to obtaining damages or the cessation of use of the incriminated product.

If these actions were carried out and recognized, in whole or in part, as justified, the Group could be forced to stop or delay the research, development, manufacture or marketing of the products covered by these actions, which would significantly affect its activities in the sector of activity concerned.

In particular, the Group could be required, in addition to the payment of financial compensation, to:

- stop manufacturing, selling or using the products in question, in a given geographical area;

- obtain, under conditions unfavorable to the Group, a license on the intellectual property rights of third parties;

- find alternative solutions so as not to infringe on the intellectual property rights of third parties, which could, in some cases, prove impossible or be costly in terms of time and financial resources, and could therefore hinder its efforts of marketing.

A procedure brought against the Group, whatever the outcome, could lead to substantial costs, disrupt its operations, compromise all or part of its business, its image and its reputation.

The Spineway group does not have to deplore any dispute relating to intellectual property rights.

The Group cannot therefore guarantee that the illicit use of its intellectual property rights will not have the effect of affecting the marketing of its products and, more generally, of harming the activities, the results, the financial situation, the development, and the outlook for the Group. Similarly, the Group cannot guarantee that it will not infringe, directly or indirectly, the intellectual property rights of third parties and that this unlawful use will not seriously affect the marketing of its products and, more generally, harming the activities, results, financial situation, development, and prospects of the Group.

The Company assigns this risk a **medium** level.

# 5.3 The risks related to a possible questioning of the Company's liability for defective products reinforced by the sector of activity

In addition to the legal warranties, the Group could be exposed to risks of its liability being called into play when using its products, in particular based on liability for defective products. In fact, spinal surgery involves significant risks of serious complications that can lead to paralysis or have fatal consequences. The tests and marketing of medical devices intended for the spine therefore carry a risk of the manufacturer's liability being called into question. Criminal complaints or legal proceedings could be filed or initiated against the Group by users (surgeons and/or hospitals), patients or regulatory authorities.

Beyond any proven defect, spine medical device players may also be involved, justified or unjustified, in litigation concerning suspected product defects. Spineway's liability could also be heavily incurred in this respect if it were proven that the implant or the instrumentation was the direct cause of the damage and that the latter did not come from the surgical act or from the healthcare establishment, nor of the distribution chain, nor of the patient himself, or, more generally, if Spineway were unable to successfully defend himself.

A claim filed under liability for defective products could force Spineway, regardless of the follow-up given to this claim, to limit the marketing of its products. Its reputation could be affected, it being understood all the same that in such a case, Spineway could turn against its subcontractors and/or suppliers of raw materials if it turns out that they are responsible for the said defect. Finally, an unfounded or unsuccessful claim could:

- prove to be long and costly for the Company ;
- permanently affect Spineway's reputation on the market ;
- divert the efforts of the management of the Company from its main activity.

To date, Spineway's liability for defective products has never been sought.

The Company has always paid particular attention to the risks related to the control and control of defective products as well as to the audits necessary to maintain this quality. In 2017, Spineway spontaneously chose to recall an instrument for exchange after having identified a potential risk linked to this instrument (which is not an implant but an instrument for locking the screw of an implant). The Company therefore favors the application of a principle of prudence and is particularly attentive to the quality of its products, in accordance with the regulations and compliance with the quality standards that it has imposed on itself.

Spineway has also taken out civil liability insurance covering its liability in the event of defective products up to a maximum compensation envelope of 10 M€, if necessary, reduced by the use already made of this annual cover at the time recourse In the event of a major failure in a flagship range, this insurance could prove to be insufficient to cover all of the pecuniary judgments liable to be pronounced against Spineway. The latter could therefore have to pay the supplement itself by drawing on its resources and thereby weaken its financial situation. The Company is also particularly vigilant to specific liability issues on the American market and will adapt its coverage accordingly with the redeployment of this market.

The Company cannot therefore guarantee that its current insurance coverage is sufficient to respond to any liability actions that may be brought against it. If its liability were so implicated, and if it were unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to insure itself in any way against liability actions of the of the products, this would have the consequence of seriously affecting the marketing of its products and, more generally, of harming the activities, the results, the financial situation, the development, and the prospects of the Group.

The Company assigns this risk a **low** level.

# APPENDIX 2

# Financial results table for the last five years

TABLEAU DES RESULTATS FINANCIERS	31/12/2018	31/12/2019	31/12/2020	31/12/2021	31/12/2022*
Capital social	1 684 407,00	4 545 710,79	463 275,94	1 576 029,77	182 109,90
Nombre d'actions ordinaires	16 844 070	454 571 079	4 632 759 445	15 760 297 542	3 642 198
Nombre d'actions à dividende prioritaire	0	0	0	0	0
Nombre maximal d'actions futures à créer	87 500 000	673 377 878	6 230 016 123	3 309 139 343	82 398
* par conversion d'obligations	70 000 000	492 857 142	5 632 759 446	694 444 444	0
* par exercice de droits de souscription	17 500 000	180 520 736	597 256 677	2 614 694 898	82 398
Chiffres d'affaires hors taxes	6 516 892	5 081 929	3 379 615	4 272 425	5 256 163
Résultat avant impôts, participation, dotations aux amort. et prov.	-3 175 503	-1 876 090	-13 067 167	-827 058	-1 547 749
Impôt sur les bénéfices (crédits d'impôts)	396 497	210 362	231 620	172 516	225 773
Participations des salariés	0	0	0	0	0
Résultat après impôts, participations et dotations aux amort. et prov.	-5 247 525	-3 331 938	-13 590 634	-1 512 848	-1 757 551
Résultat distribué	0	0	0	0	0
Par action résultat après impôts avant dotations aux amort. et prov.	-0,12	0,37	-0,0028	0,0000	-0,2542
Par actions résultat après impôts et dotations aux amort. et prov.	-0,31	0,73	-0,0029	-0,0001	-0,4826
Dividende attribué à chaque action	0,00	0,00	0,00	0,00	0,00
Effectif moyen des salariés de l'exercice	42	28	25	31	35
Montant de la masse salariale	-2 127 123	-1 524 001	-1 450 645	-1 711 609	-2 741 085
Cotisations sociales et avantages sociaux	-857 059	-674 558	-579 405	-684 326	-1 043 146

\*suite au regroupement d'actions de septembre 2022, une action nouvelle correspond à 40 000 actions anciennes. Les avantages consentis au titre des BSA ont été mécaniquement divisés par 40 000.