



A French société anonyme with capital of €757,566.10

Registered office: 58, Avenue de Wagram – 75017 Paris

Paris Trade and Companies Register number 439 685 850.

2018 REGISTRATION DOCUMENT

Including the Annual Financial Report

This document is an English-language translation of Voluntis' Document de Référence 2018, which was filed with the AMF (French Financial Markets Authority) on April 26, 2019. Only the French version of the Document de Référence is legally binding



This Registration Document was registered on 26 April 2019 under the number R.19-013 in accordance with Article 212-13 of the General Regulations of the French Financial Market Authority (AMF). It may not be used in support of a financial transaction unless it is accompanied by a transaction note endorsed by the AMF. This document was drawn up by the issuer and engages the responsibility of its signatories.

In accordance with the provisions of Article L. 621-8-1-I of the French Financial and Monetary Code, the registration was done after the AMF had verified that the document was complete and understandable, and the information provided therein was consistent. It does not imply that the AMF has verified the accounting and financial information presented herein.

This document is available free of charge from the Company's head office and in electronic form on the AMF website (www.amf-france.org) and on the Company's website (www.voluntis.com).

TABLE OF CONTENTS

1.	PERSONS RESPONSIBLE.....	14
1.1	Person responsible for the Registration Document	14
1.2	Statement of the person responsible	14
1.3	Person responsible for the financial information.....	14
2.	STATUTORY AUDITORS	15
2.1	Principal Statutory Auditors	15
2.2	Alternate Statutory Auditor	15
2.3	Statement of the fees paid to the Statutory Auditors	15
3.	SELECTED FINANCIAL INFORMATION.....	16
4.	RISK FACTORS	18
4.1	Risks related to the business sector, the markets in which the Group operates and its economic environment.....	19
4.1.1	Risks relating to the existence of alternative technologies and the emergence of new competing technologies.....	19
4.1.2	Risks related to the setting of prices and changes in medical device reimbursement policies ..	19
4.1.3	Risks relating to the very significant size of the Group's main competitors in the markets	20
4.1.4	Risks related to the economic and financial environment	21
4.2	Risks related to the Group's business	22
4.2.1	Risks related to the partnership agreements necessary for the development and/or marketing of the Group's products	22
4.2.2	Risks related to the market launch of the Group's products and their marketing	22
4.2.3	Risks related to the Group's customers	24
4.2.4	Risks related to the Group's technology	25
4.2.5	Risks related to clinical trials, to which the Group submits its products at its own initiative.....	26
4.2.6	Risks related to the Group's IT service providers	27
4.3	Legal and regulatory risks	27
4.3.1	Risks related to various regulatory frameworks	27
4.3.2	Risks invoking liability on account of the products	30
4.3.3	Risks related to intellectual property	31
4.3.4	Risks related to statutory audits	35
4.4	Risks related to the Group organisation and development strategy.....	35
4.4.1	Risks related to the implementation of the Group strategy.....	35
4.4.2	Risks related to the management of the Group's internal growth	35
4.4.3	Risks related to the dependence on qualified personnel and key management personnel and the inability to attract new employees that the Group will need for its development.....	36
4.4.4	Risks related to the possible realisation of external growth operations	36
4.5	Financial risks.....	37
4.5.1	Liquidity risk	37
4.5.2	Risks related to research tax credit	38
4.5.3	Dilution risk.....	39
4.5.4	Risks related to indebtedness and restrictive financing clauses.....	39
4.5.5	Risks related to the future use of tax losses carried forward	40
4.5.6	Credit risk	40
4.6	Market risks	40
4.6.1	Exchange rate risk	40
4.6.2	Interest rate risk	41

4.7	Insurance and risk coverage	41
4.8	Judicial and arbitration proceedings	43
5.	COMPANY INFORMATION.....	44
5.1	History and evolution of the Company	44
5.1.1	Legal and commercial name of the Company	44
5.1.2	Location and registration number of the Company	44
5.1.3	Date of incorporation and duration	44
5.1.4	Company's head office, legal form, legislation governing its activities	44
5.1.5	Important events in the development of the Group's operations	44
5.2	Investments	47
5.2.1	Principal investments made during the last two financial years	48
5.2.2	Principal current investments	48
5.2.3	Principal future investments	49
6.	BUSINESS OVERVIEW	50
6.1	Overview of activities and developments during the past financial year	50
6.2	The emergence of therapeutic software	51
6.2.1	Digital therapeutics: a new industrial sector	53
6.2.2	Definition of therapeutic software	54
6.2.3	Digital transformation of health: high stakes for public health	55
6.2.4	Less-than-optimal treatment efficacy in the real world	56
6.2.5	Voluntis and therapeutic software	56
6.2.6	Business model	58
6.3	Digital therapeutics in diabetes: at commercial stage	59
6.3.1	Diabeo® for diabetes treated on an insulin regimen with multiple injections or pump	60
6.3.2	Insulia® for people with type 2 diabetes (noninsulin-dependent diabetes)	61
6.3.3	Business model based on reimbursement from payers	64
6.3.4	Strategic partnerships and dual distribution policy	65
6.4	Digital therapeutics in oncology: in development	68
6.4.1	Cancer and managing symptoms	69
6.4.2	A solution targeting a range of different cancers	70
6.4.3	Development of solutions in partnership with the pharmaceutical industry	71
6.5	The regulatory environment for therapeutic software	71
6.5.1	Regulation of therapeutic software as medical devices	71
6.5.2	French regulation of telemedicine	72
6.5.3	Data privacy regulations Voluntis is committed to protecting data privacy.	73
6.5.4	Legal and economic framework for e-health and telemedicine solutions	74
6.6	Voluntis: organisation and growth trajectory	74
6.7	Technological platform	76
6.8	Priorities in addition to diabetes and oncology	78
6.9	The competitive landscape and key success factors	81
6.10	Clinical trials and Scientific Advisory Committees	84
6.10.1	Clinical studies in diabetes	84
6.10.2	Clinical trials in oncology	88
6.10.3	Scientific Advisory Boards	89
6.10.4	Study list and references	92

7.	ORGANISATIONAL CHART	94
7.1	Group Organisation	94
7.2	List of subsidiaries, branches, and secondary establishments	94
7.3	Principal intra-group flows.....	94
7.3.1	International Sale <i>Commission</i> Agreement	94
7.3.2	Service and Expertise Agreement.....	94
7.3.3	Credit Facility Agreement	95
8.	PROPERTY, PLANT AND EQUIPMENT	96
8.1	Description of properties	96
8.2	Environmental issues.....	96
9.	REVIEW OF THE FINANCIAL POSITION	97
9.1	Overview	97
9.1.1	Consolidated financial statement.....	97
9.1.2	Group Overview	97
9.1.3	Main factors having an impact on business and results	98
9.2	Financial position	98
9.2.1	Comparison of financial statements for the financial years ended 31 December 2016 2017 and 31 December 2018.....	98
9.2.2	Revenue and operating income from the 2017 and 2018 financial years	99
9.2.3	Net income breakdown.....	104
9.2.4	Net income and net earnings per share	104
9.2.5	Presentation and analysis of the balance sheet at 31 December 2017 and 2018.....	105
9.2.6	Proposed appropriation of income for 2018	109
9.2.7	Non-deductible expenses.....	109
10.	CASH AND CAPITAL	110
10.1	Capital, liquidity, and financing sources	110
10.1.1	Capital and quasi-capital financing	110
10.1.2	Financing through loans	111
10.1.3	Financing through loans since year-end	111
10.2	Cash flow for the 2017 and 2018 financial years	112
10.2.1	Net cash flows/(used in) operating activities.....	112
10.2.2	Net cash flows from/(used in) investing activities.....	112
10.2.3	Net cash flows from/(used in) financing activities	112
10.3	Information on loan terms and financing structure.....	113
10.4	Restriction on the use of capital	113
10.5	Financing sources required for the future	113
11.	RESEARCH & DEVELOPMENT, PATENTS, LICENCES.....	114
11.1	Innovation policy.....	114
11.2	Development costs.....	114
11.3	Patents and patent applications.....	115
11.3.1	Overview	115
11.3.2	As of the date of this Registration Document, the patents and patent applications used by the Group are those belonging to the Company.	115
11.3.3	Details of the four patent families and patent applications.....	117
11.4	Partnership, research, service, and licensing contracts awarded by the Group or to the Group	120
11.4.1	Contracts in the field of diabetes treatment	120
11.4.2	Other contracts (licensing and partnership)	120

11.5	Trademarks and domain names	121
11.5.1	Trademarks	121
11.5.2	Domain names	122
11.6	Intellectual property rights pledged	123
12.	TRENDS	124
12.1	Key trends since the end of the last financial year ended 31 December 2018	124
12.2	Known trend, uncertainty, request for commitment, or event reasonably likely to influence the Group's prospects	124
13.	PROFIT FORECASTS OR ESTIMATES	125
14.	ADMINISTRATIVE, MANAGEMENT, SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT	126
14.1	Officers and member of the Board of Directors	126
14.1.1	Management	126
14.1.2	Board of Directors	127
14.1.3	Other corporate offices	129
14.1.4	Statements about management and members of the Board of Directors	131
14.1.5	Profiles of members of management and the Board of Directors	132
14.2	Conflicts of interest in the administrative bodies and executive management	137
15.	COMPENSATION AND BENEFITS	140
15.1	Compensation of corporate officers	140
15.2	Sums provisioned by the Company for the payment of pensions, retirements, and other benefits to corporate officers	151
15.3	Securities giving access to the Company's share capital allocated to or subscribed by corporate officers	151
15.4	Principles and criteria for determining, distributing and assigning the fixed, variable and exceptional components composing the total compensation and benefits of any kind attributable to the Chairman of the Board of Directors, Chief Executive Officer and Deputy Chief Executive Officers	151
15.4.1	Chairman of the Board of Directors	151
15.4.2	Pierre Leurent, Chief Executive Officer	152
15.4.3	Romain Marmot, Deputy Chief Executive Officer	153
15.4.4	Alexandre Capet, Deputy Chief Executive Officer	155
15.4.5	Resolutions submitted to a vote by the shareholders	156
15.5	Summary report on trading by officers and the persons referred to in Article L. 621-18-2 of the French Financial and Monetary Code in the shares of the Company during the past year.	157
16.	FUNCTIONING OF ADMINISTRATIVE AND MANAGEMENT BODIES	159
16.1	Company Management	159
16.2	Information on contracts between the Company or its subsidiary and the Company's officers	159
16.3	Board of Directors and Special Committees - Corporate Governance	159
16.3.1	Board of Directors	159
16.3.2	Committees	163
16.4	Corporate Governance	169
16.5	Internal control and risk management procedures set up by the Company	170
16.5.1	Definition, objectives and limits of internal control	170
16.5.2	Organisation of internal control	171

17. EMPLOYEES	173
17.1 Human Resources.....	173
17.1.1 Organisational chart as of the date of this Registration Document.....	173
17.1.2 Numbers and breakdown of workforce	173
17.1.3 Employee representation	174
17.2 Shareholding and stock options of corporate officers	174
17.3 Employee shareholding in the Company	174
17.4 Profit-sharing and incentive schemes	174
18. MAJOR SHAREHOLDERS	175
18.1 Allocation of share capital and voting rights.....	175
18.2 Stock market information	176
18.3 Substantial shareholders not represented on the Board of Directors	176
18.4 Voting rights of the major shareholders	176
18.5 Control of the Company	176
18.6 Agreements that can result in a change in control.....	177
18.7 Status of pledged shares of the Company.....	177
18.8 Items likely to have an impact in the event of a public offering	177
18.8.1 Structure of the Company's share capital	177
18.8.2 Restrictions on voting rights and share transfers under the Articles of Association or clauses of agreements brought to the Company's attention in accordance with Article L. 233-11 of the French Commercial Code.....	177
18.8.3 Direct or indirect capital interests in the Company of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code	177
18.8.4 List of holders of any securities conferring special rights of control and a description of these securities.....	177
18.8.5 Control mechanisms provided for under any employee shareholding system, when the rights of control are not exercised by said employees	177
18.8.6 Agreements between shareholders of which the Company is aware and which may result in restrictions on share transfers and the exercise of voting rights	177
18.8.7 Rules on the appointment and replacement of members of the Board of Directors as well as on the amendment of the Company's Articles of Association;	177
18.8.8 Powers of the Board of Directors, in particular, with regard to the issue or buyback of shares	178
18.8.9 Agreements signed by the Company that would be amended or terminated by a change of control of the Company	178
18.8.10 Agreements providing for compensation for Board members or employees, if they resign or are made redundant without just cause or if their employment ceases because of a takeover bid	178
19. RELATED-PARTY TRANSACTIONS	179
19.1 Intra-group agreements.....	179
19.2 Related-party transactions	179
19.3 Statutory Auditors' reports on regulated agreements.....	179
19.3.1 Special report of the Statutory Auditors on regulated agreements established in relation to the financial year ended 31 December 2017	179
19.3.2 Rapport spécial du commissaire aux comptes sur les conventions réglementées établi au titre de l'exercice clos le 31 décembre 2018	182

20. FINANCIAL INFORMATION.....	185
20.1 Consolidated financial statements prepared according to the IFRS for the financial year ended 31 December 2018.....	185
Note 1 : Description of the Group and its business	190
1.1 The Voluntis Group.....	190
1.2 Key events during the year	191
Note 2 : Scope of consolidation	193
2	193
2.1 The Voluntis Company.....	193
2.2 List of consolidated entities	193
2.3 Consolidation methods	193
Note 3 : ACCOUNTING PRINCIPLES APPLIED BY THE GROUP AND DECLARATION OF CONFORMITY	193
3	193
3.1 Declaration of conformity	193
3.2 Accounting principles and methods	194
3.2.1 New standards adopted by the European Union and applicable at 1 January 2018:	194
3.2.2 New standards adopted by the European Union whose application was not mandatory at 31 December 2018:	196
3.3 Accounting judgements and estimates used to prepare the financial statements.....	197
3.4 Functional currencies and currency in which the consolidated financial statements are presented	197
3.5 Intangible assets.....	198
3.5.1 Research and development	198
3.5.2 Other intangible assets.....	199
3.6 Tangible assets.....	199
3.7 Impairment of tangible and intangible assets	199
3.8 Financial assets.....	200
3.8.1 Non-current financial assets	200
3.8.2 Trade and other receivables.....	200
3.8.3 Cash and cash equivalents	200
3.9 Capital.....	200
3.10 Share-based payments	200
3.11 Financial liabilities	201
3.11.1 Financial liabilities at amortised cost	201
3.11.2 Liabilities measured at fair value through profit or loss	201
3.12 Conditional advances.....	201
3.13 Provisions	202
3.13.1 Provisions	202
3.13.2 Employee commitments: employee benefits	202
3.14 Revenue	202
3.14.1 Revenue recognition.....	202
3.14.2 Other revenue	204

3.15	Leases	205
3.16	Income tax	205
3.16.1	Current income tax	205
3.16.2	Deferred tax.....	205
3.17	Segment reporting	206
3.18	Other operating income and expense.....	206
Note 4 :	NOTES TO THE CONSOLIDATED INCOME STATEMENT	207
2	207	
3	207	
4	207	
4.1	Operating income	207
4.2	External expenses	208
4.3	Staff costs	208
4.4	Share-based payments	209
4.4.1	Warrants (BSA):.....	209
4.4.2	Founders' stock options (BSPCE):.....	209
4.4.3	Stock options (OSA):	210
4.4.4	Free share allocations:	210
4.4.5	Measurement of BSAs, BSPCEs and OSAs	211
4.5	Depreciation, amortisation.....	212
4.6	Cost of net financial debt.....	213
4.7	Income tax	213
4.7.1	Tax expense.....	213
4.7.2	Tax proof	213
4.8	Net earnings per share	214
Note 5 :	Notes to the consolidated statement of financial position.....	215
5	215	
5.1	Intangible assets.....	215
5.2	Tangible assets.....	216
5.3	Non-current financial assets	216
5.4	Trade and other receivables	217
5.5	Cash	218
5.6	Share capital	218
5.7	Provisions	219
5.8	Interest-bearing loans	220
5.8.1	Changes during the reporting periods.....	220
5.8.2	Breakdown by due date	220
5.8.3	Convertible bond loans.....	221
5.8.4	"Venture loan" financing contract combined with the issue of share subscription warrants...	221
5.8.5	Interest free loan:	221
On 24 June 2014, the Group was granted an interest free loan for innovation in the amount of €850k with Bpifrance Financement. The funds were made available in full in one single drawdown. The term of amortisation of the loan is five years, and the first repayment is due on 06/01/2016.		221

5.9	Other non-current liabilities.....	222
5.10	Current liabilities.....	222
5.11	Fair value of financial assets and liabilities.....	222
Note 6 :	Application of IFRS 15 Reconciliation table	224
Note 7 :	Management and measurement of financial risks	226
6		226
7		226
7.1	Interest rate risk	226
7.2	Liquidity risk	226
7.3	Credit risk	226
7.4	Exchange rate risk	226
Note 8 :	Other information.....	227
8		227
8.1	Off-balance sheet commitments	227
8.2	Commitments linked to operating leases.....	227
8.3	Headcount.....	228
8.4	Related party transactions.....	228
8.5	Compensation of senior executives	228
8.6	Post-closing events	228
20.2	Statutory Auditors' reports on the consolidated financial statements prepared according to IFRS, as adopted by the European Union for the financial year ended 31 December 2018.....	223
	Exercice clos le 31 décembre 2018	224
	Rapport des commissaires aux comptes sur les comptes consolidés	224
20.3	Dividend distribution policy.....	229
20.4	Judicial and arbitration proceedings	229
20.5	Significant change in the financial or commercial position	229
20.6	Results for the last five years.....	229
21.	ADDITIONAL INFORMATION	231
21.1	Share capital	231
21.1.1	Amount of the share capital.....	231
21.1.2	Non-equity securities.....	231
21.1.3	Acquisition by the Company of its own shares – Treasury shares and share buyback.....	231
21.1.4	Financial assets giving access to capital.....	233
21.1.5	Authorised capital.....	242
21.1.6	Information on the capital of any member of the Group which is the subject of an option or of a conditional or unconditional agreement to put it under option	245
21.1.7	History of the share capital	245
21.2	Memorandum and Articles of Association.....	247
21.2.1	Corporate purpose (Article 3 of the Articles of Association)	247
21.2.2	Statutory regulations or other regulations relating to members of the administrative and management bodies	248
21.2.3	Rights, privileges, and restrictions on shares.....	251
21.2.4	Methods for changing shareholders' rights	253
21.2.5	General Meetings of Shareholders	253
21.2.6	Provisions that may delay, defer or prevent a change in control	254
21.2.7	Crossing of statutory thresholds	255

21.2.8	Special provisions governing changes in capital	255
22.	MATERIAL CONTRACTS	256
22.1	Partnership agreement with AstraZeneca of 24 November 2015 (eCo Project).....	256
22.1.1	Purpose of the collaboration agreement	256
22.1.2	Financial consideration.....	256
22.1.3	Intellectual property.....	256
22.1.4	Term	257
22.1.5	Termination conditions.....	257
22.2	Partnership and licensing agreement with Sanofi France (Diabeo Project)	257
22.2.1	Purpose of the partnership agreement.....	257
22.2.2	Financial consideration.....	257
22.2.3	Intellectual property.....	259
22.2.4	Term	259
22.2.5	Termination conditions.....	260
22.2.6	Other contractual provisions.....	260
22.3	Non-exclusive licence and collaboration agreement with Sanofi (for the distribution of Insulia) 260	
22.3.1	Purpose of the licensing and services agreement.....	260
22.3.2	Financial consideration.....	261
22.3.3	Intellectual property.....	261
22.3.4	Term	261
22.3.5	Termination conditions.....	261
22.4	Non-exclusive licence and services agreement with Verily	261
22.4.1	Purpose of the licensing and services agreement.....	262
22.4.2	Financial consideration.....	262
22.4.3	Intellectual property.....	262
22.4.4	Termination conditions.....	262
22.5	Non-exclusive licence and services agreement with Onduo	263
22.5.1	Purpose of the licensing and services agreement.....	263
22.5.2	Financial consideration.....	263
22.5.3	Intellectual property.....	263
22.5.4	Term	264
22.5.5	Termination conditions.....	264
22.6	Bond issue agreement entered into with Kreos Capital V (UK) Ltd	264
22.6.1	Terms of the subscribed Kreos Bonds (Tranche A)	264
22.6.2	Terms of the Kreos Bonds to be subscribed (Tranche B).....	265
22.6.3	Terms of the Kreos Bonds to be subscribed (Tranche C).....	266
22.6.4	Warrants issued for Kreos Capital V (Expert Fund) L.P.	266
22.6.5	Collateral granted	266
22.6.6	Company undertakings	267
22.6.7	Prepayment	267

23.	INFORMATION FROM THIRD PARTIES, EXPERT STATEMENTS, AND DECLARATIONS OF INTEREST	269
23.1	Name of experts.....	269
23.2	Name of third parties	269
24.	PUBLICLY ACCESSIBLE DOCUMENTS	270
25.	SHAREHOLDING INFORMATION	271
26.	CROSS-REFERENCE TABLE	273
27.	GLOSSARY	275
28.	APPENDIX	278
28.1	Company financial statements prepared in accordance with French standards for the financial year ended 31 December 2018	278
28.2	Statutory Auditors' report on financial statements prepared according to French accounting standards for the financial year ended 31 December 2018.....	299

This Registration Document has been prepared in accordance with Appendix XXV of Regulation (EC) No. 809/2004 dated 29 April 2004.

Note

Definitions

In this Registration Document, unless otherwise specified:

- the term "Registration Document" refers to this Registration Document;
- the terms "Company" or "Voluntis" refer to the company Voluntis having its head office at 58, Avenue de Wagram, 75017 Paris, registered in the Paris Trade and Companies Register under the number 439 685 850;
- the term the "Group" refers to the group of companies formed by the Company and its subsidiary, Voluntis Inc., the principal establishment whereof is located at 125, Cambridge Park Drive Suite 304, Cambridge, MA 02142, USA, registered in the State of Delaware under the number 73350928.

A glossary defining some of the terms used in the Registration Document can be found in Chapter 26.

In accordance with Article 28 of Commission Regulation (EC) No. 809/2004, the following information is incorporated by reference into the Registration Document:

- the consolidated financial statements for the year ended 31 December 2017, included in Section 20.1 of the Base Document registered by the AMF on 17 April 2018 under number I. 18-016;
- the Statutory Auditors' Reports on the consolidated financial statements for the year ended 31 December 2017, in Section 20.2 of the Base Document registered by the AMF on 17 April 2018 under number I. 18-016.

The Registration Document is available in electronic form on the AMF website (www.amf-france.org) and on the Company's website (www.voluntis.com).

Notice

Information on the market and competition

Chapter 6 of the Registration Document "*Business overview*", contains information on the Group's markets and its competitive position. This information comes from studies carried out by external sources. The publicly available information, which the Company considers as reliable, was not verified by an independent expert, and the Company cannot guarantee that a third party using different methods to assemble, analyse or compute data on these markets would obtain the same results.

Prospective information

The Registration Document contains information on the Group's prospects and areas of development. Such information is sometimes identified by the use of the future, conditional or prospective terms such as "consider", "envisage", "think", "aim", "expect", "hear", "have to", "ambition", "estimate", "believe", "wish", "be able to" or, where appropriate, the negative form of these terms, or any other similar variant or terminology. This information is not historical data and should not be construed as guarantees that the facts and data set out may actually occur. This information is based on data, assumptions and estimates considered to be reasonable by the Company. They are likely to evolve or be modified due to uncertainties related in particular to the economic, financial, competitive and regulatory environment. This information is mentioned in different sections of the Registration Document and contains data relating to the Group's intentions, estimates and objectives concerning, in particular, the market in which it operates, its strategy, growth, results, financial position, cash position and forecasts. The forward-looking information mentioned in the Registration Document is given only on the date of the Registration Document. The Group operates in a competitive and constantly changing environment. Thus, it cannot anticipate all the risks, uncertainties or other factors that could affect its business, their potential impact on its business or the extent to which the materialisation of a risk or a combination of

risks could have significantly different results from those mentioned in any forward-looking information, it being specified that none of this information constitutes a guarantee of actual results.

Risk factors

Investors are invited to read carefully the risk factors described in Chapter 4 "*Risk factors*" of the Registration Document before taking any investment decision. The occurrence of all or part of these risks is likely to have a material adverse impact on the Company's business, financial position, results or prospects. In addition, other risks, not yet identified or considered insignificant by the Company at the date of the Registration Document, could also have a material negative impact.

1. PERSONS RESPONSIBLE

1.1 Person responsible for the Registration Document

Pierre Leurent, Chief Executive Officer.

1.2 Statement of the person responsible

After having taken all reasonable measures to this effect, I certify that the information contained in the Registration Document is, to the best of my knowledge, true to the facts and does not contain any omission that would affect its import.

I hereby certify that, to the best of my knowledge, the financial statements are prepared in accordance with the applicable accounting standards and that they provide a true and fair view of the assets, financial position and income of the Company and all of the companies included in the scope of consolidation, and that the items of the management report contained in the Registration Document as stated in the cross-reference table in Section 26 presents a true reflection of the changes in the business, results and financial position of the company and of all Group companies, and that it describes the main risks and uncertainties that they face.

I have obtained a letter of completion from the Statutory Auditors, in which they state that they have verified the information on the financial situation and accounts given in the Registration Document and read the entire Registration Document.

Issued in Paris,
26 April 2019

Pierre Leurent
Chief Executive officer

1.3 Person responsible for the financial information

Matthieu Plessis

Chief Administrative & Financial Officer

Address: 22, Quai Gallieni, 92150 Suresnes

Telephone: +33 (0) 1 41 38 39 20

Fax: + 33 0) 1 41 38 39 26

E-mail: investors@voluntis.com

2. STATUTORY AUDITORS

2.1 Principal Statutory Auditors

Ernst & Young et Autres, a simplified joint-stock company with variable capital, whose registered office is at 1-2, Place des Saisons, Paris La Défense 1, 92400 Courbevoie, registered in the Nanterre Trade and Companies Register under the number 438 476 913, represented by Franck Sebag, partner.

Date of commencement of the first term of office: 25 June 2008

Date of expiry of the current term of office: Annual General Meeting approving the financial statements for the year ending 31 December 2019.

RBB Business Advisors, a French société anonyme, whose registered office is at 133 bis, Rue de l'université 75007 PARIS, registered in the Paris Trade and Companies Register under the number 414 202 341, represented by Jean-Baptiste Bonnefoux. Deputy chief executive officer.

Date of commencement of the first term of office: 9 May 2018

Date of expiry of the current term of office: Annual General Meeting approving the financial statements for the year ending 31 December 2023.

2.2 Alternate Statutory Auditor

Auditex, simplified joint stock company with variable capital, having its head office at 1-2, Place des Saisons, Paris La Défense 1, 92400 Courbevoie, registered in the Nanterre Trade and Companies Register under the number 377 652 938, represented by Christian Scholer, partner.

Date of commencement of the first term of office: 25 June 2008

Date of expiry of the current term of office: Annual General Meeting approving the financial statements for the year ending 31 December 2019.

During the period covered by the historical financial information, there has been no resignation or removal of the Statutory Auditor.

2.3 Statement of the fees paid to the Statutory Auditors

In € thousands	Ernst & Young et Autres		RBB Business Advisors	
	2018	2017	2018	2017
Statutory auditing, certification, examination of individual and consolidated financial statements	145	80	30	0
Other services and due diligence directly related to the Statutory Auditor's mission	221	0	8	0
Subtotal Audit	366	80	38	0
Other tax services	0	0	0	0
Other services and due diligence	0	0	0	0
Subtotal Other services	0	0	0	0
TOTAL	366	80	38	0

The statutory auditors' fees for the 2018 financial year include exceptional items totalling €248k for the preparation of the consolidated financial statements, including historical comparables that required an additional audit and specific work carried out in connection with the Company's initial public offering on the Euronext market in Paris.

3. SELECTED FINANCIAL INFORMATION

The selected financial information presented in Chapter 3 is derived from the consolidated financial statements of the Group for the years ended 31 December 2017 and 2018, which appears in Sections 20.1 and 18 respectively of the Base Document registered by the AMF on 17 April 2018 under number I. 18-016 and the Registration Document.

This financial information should be read in conjunction with (i) the review of the results and financial position of the Company presented in Chapter 9 of the Registration Document and (ii) the review of the Company's cash and capital presented in Chapter 10 of the Registration Document.

Extracts of the consolidated financial information for the years ended 31 December 2016, 2017 and 2018 (IFRS)

Financial information selected from the consolidated income statement:

In € thousands	Years ended December 31		
	2018	2017	2016
Revenue	4,533	7,302	10,272
Other operating revenue	637	1,095	987
Total operating revenue	5,170	8,396	11,258
Staff costs	(12,245)	(10,423)	(8,370)
Other operating income and expenses	(6,606)	(6,048)	(6,256)
Depreciation and amortisation, net. and operating provisions	(1,827)	(1,550)	(970)
Operating income	(15,512)	(9,625)	(4,338)
Financial income	(427)	(423)	(472)
Taxes	3	22	(46)
Net income – Equity holders of the parent	(15,935)	(10,026)	(4,857)
EBITDA¹	(13,685)	(8,075)	(3,367)

¹EBITDA (earnings before interest, taxes, depreciation, and amortisation) is a key indicator for the Group. It is defined as operating income excluding current and non-current depreciation, amortisation, impairment and provisions.

Financial information selected from the consolidated balance sheet:

In € thousands	Years ended December 31		
	2018	2017	2016
Assets			
Net intangible assets	1,901	2,489	2,676
Net tangible assets	563	764	277
Non-current financial assets	253	241	114
Other non-current assets	1,016		
<i>Non-current assets</i>	3,732	3,494	3,067
Trade and other receivables	1,505	299	3,435
Other current financial assets	91		
Other current assets	5,445	2,322	2,257
Cash	19,783	1,845	5,831
<i>Current assets</i>	26,823	4,466	11,522
Total	30,555	7,960	14,589
	2018	2017	2016
Liabilities and shareholders' equity			
<i>Shareholders' equity</i>	17,301	(1,127)	2,096
Non-current financial debts	2,199	252	541
Non-current provisions and other non-current liabilities	3,420	463	452
<i>Non-current liabilities</i>	5,618	714	993
Current financial debts	1,440	4,003	6,467
Trade and other payables	6,196	4,370	5,033
<i>Current liabilities</i>	7,636	8,373	11,500
Total	30,555	7,960	14,589

Financial information selected from the consolidated cash flow table:

In € thousands	Years ended December 31		
	2018	2017	2016
Cash flow generated by operations	(14,726)	(5,396)	(4,610)
Cash flow from investing activities	(1,336)	(1,900)	(1,516)
Cash flow from financing activities	33,993	3,339	9,394
CHANGE IN CASH FLOW	17,931	(3,958)	3,269
Impact of exchange rate fluctuations	7	(21)	10
OPENING CASH BALANCE	1,845	5,824	2,545
CLOSING CASH BALANCE	19,783	1,845	5,823

4. RISK FACTORS

Investors are invited to consider all the information included in the Registration Document, including the risk factors described in this chapter, before deciding to acquire or subscribe to the Company's shares. The latter carried out a review of the risks that could have a material negative impact on the Group, its business, financial situation, results, prospects or its ability to achieve its objectives and considers that there are no other significant risks apart from those presented.

However, the attention of investors is drawn to the fact that other risks, unknown or whose realisation is not considered at the date of the Registration Document, which may have a material negative impact on the Group, its business, financial situation, results, prospects, can or could exist.

The first risk factor for each section below is, according to the Company's assessment at the date of the Registration Document, the most important risk factor for that section. Nevertheless, the occurrence of new event, either inside or outside the Group, may change this hierarchy in the future.

The main risk factors facing the Group are as follows:

- risks related to the business sector, the markets in which the Group operates and its economic environment, and in particular the risks associated with:
 - o the existence of alternative technologies (such as the artificial pancreas or stem cells) and the emergence of new competing technologies,
 - o the reimbursement policy for medical devices, as the Group's strategy is based in part on the payment agencies taking charge of its solutions, and
 - o the very significant size of the Group's main competitors (such as Novo-Nordisk-Glooko, Sanofi, Google, Roche or Medtronic);
- risks related to the Group's business, and in particular risks related to:
 - o the Group's partnerships, as the Group's strategy is based in part on the mobilization of its partners to develop and market its products,
 - o the marketing of the Group's products, the latter being dependent on the rate of adherence of health professionals and patients, and their marketing, as the Group has limited marketing experience,
 - o to the Group's customers, some of whom have significant market share and bargaining power or may be subject to insolvency problems, and
 - o the clinical development of the Group's products, any failure during one of the various trial phases for a given indication could delay or even lead to the termination of the development and/or marketing of the product concerned;
- legal risks, and in particular the risks associated with them:
 - o the various regulatory frameworks applicable to them, whether they relate in particular to the fact that the Group collects and uses its patients' personal data or that the Group's products are considered medical devices (requiring CE marking in Europe and, in the United States, prior authorization from the Food and Drug Administration), and
 - o the possible liability of the Group for its products;

- risks related to the Group's organization and governance, including risks related to the Group's ability to implement its strategy, manage its external growth and retain key personnel and attract the new employees needed for its development; and

financial risks, including liquidity risk, although the Company believes it will be able to meet its commitments over the next twelve months.

4.1 Risks related to the business sector, the markets in which the Group operates and its economic environment

4.1.1 Risks relating to the existence of alternative technologies and the emergence of new competing technologies

Many companies are actively involved in the discovery, research, development and marketing of digital healthcare products. This market is marked by intense competition among participants, some of whom are major players in the medical technology sector with significant resources and proven experience in development, manufacturing and marketing (see Section 4.1.2 of the Registration Document for more details).

Even if the time required for the development of a competing technology and its market launch (clinical studies, obtaining the EC marking and/or the related FDA approval, agreement for the reimbursement of social organisations, private insurance, etc.) may be relatively long, a competitor could develop a technology similar to that of the Group and with characteristics identical or superior in whole or in part to those of the companion solution developed by the Group.

Similarly, although the Group is devoting significant efforts to perfecting its existing technology, there is no guarantee that it will maintain its technological edge over the long term or that it will be able to evolve its products at the pace of market needs. Thus, potentially more effective, alternative technologies under development (such as artificial pancreas or stem cells) or other potentially more effective, safer and/or less expensive techniques not yet known, could be marketed in a more or less near future.

The marketing of any of these products could hinder the Group's development, reduce its market share, or even make its technological platform obsolete, which could have a material negative impact on the Group, its business, financial situation, results, development or prospects.

4.1.2 Risks related to the setting of prices and changes in medical device reimbursement policies

Part of the Group's commercial strategy lies in the fact that its paying bodies accept its solutions, in the same way as an approved healthcare product, available on prescription and with proof of efficacy. In order to enable the Group to successfully market its products and, as a result, to generate revenue, it is essential for it to achieve acceptable price and reimbursement levels from government authorities and bodies in charge of public or private health insurance plans. The Group is also required to set commercially viable price levels for each of its products that are also acceptable to its partners and third-party payers.

Medical device reimbursement policy

Government authorities and public or private bodies strive to control healthcare expenditure by limiting both the level of coverage and the coverage of certain products or procedures, particularly innovative products or procedures. There is constant economic, regulatory and political pressure to limit the cost of procedures involving medical devices. Third party payers are increasingly questioning the prices of medical devices and many paying third parties may either refuse to reimburse or reduce the reimbursement rates for certain devices.

Moreover, reimbursement varies from one country to another. However, the digital healthcare applications sector is very new and its therapeutic value is not assessed in the same way in all the countries in which the Group wishes to market its products.

Therefore, despite the certifications already obtained and although the Group relies on clinical studies to prove the safety or therapeutic efficacy of each of its products, it cannot guarantee that it will be eligible under reimbursement conditions in the United States, Europe or in the other main markets in which it wishes to market its products. Also, the Group cannot guarantee the coverage and reimbursement levels of the products it develops, encouraging its customers, healthcare professionals and patients to integrate such software in the treatment of the diseases they target.

The Group also capitalises on experimental reimbursement mechanisms set up by the authorities or paying bodies in different countries to test innovative payer models for covering digital therapies and/or telemedicine solutions. This is notably the case of the ETAPES program in force in France, which establishes, via the Social Security Finance Act, a framework for managing remote medical monitoring solutions for a period of four years. Nevertheless, as the future conditions for reimbursement beyond this period were not yet determined at the date of the Registration Document, the Group cannot guarantee the sustainability of these financing arrangements.

Moreover, the reimbursement schemes that the Group uses are not necessarily specific to the solutions developed by the Group and other companies are, in this context, able to capitalise on these systems themselves, even when they do not provide the same level of technicality and/or clinical evidence or safety.

Finally, although health policies tend to favour the digitisation of the healthcare organisation and the increasing role of the patient in the management of his/her illness, new legislative or administrative reforms in reimbursement systems, particularly in the United States, could substantially reduce the reimbursement of software developed by the Group (or even result in a refusal to insure these products). Therefore, the Group is, or will not, be in a position to foresee any changes over time in the coverage and reimbursement conditions that it might have obtained.

Setting of product prices by the Group

In addition, the Group's ability to set commercially viable prices for each software programme, enabling it to generate profits, depends on many other factors, including the cost of development, maintenance and price of the product, its characteristics compared to those of competing or alternative medical devices, the prices of these devices and the type of diseases covered by the companion solutions.

If market, reimbursement and competition conditions or any other event that has occurred during the development phases, clinical study and marketing of the products in question were to jeopardise their commercial interest, the Group could decide to abandon the marketing of certain software in all or some of the targeted territories.

The occurrence of one of these risks could have a material negative impact on the Group, its business, financial situation, results, development or prospects.

4.1.3 Risks relating to the very significant size of the Group's main competitors in the markets

The digital therapeutics sector, particularly in diabetes, is a competitive market where large pharmaceutical companies have established themselves by mobilising internal expertise or by developing multi-stakeholder ecosystems through partnerships (Novo-Nordisk-Glooko), equity interests (Sanofi-Omada), the creation of joint-ventures (Sanofi-Verily) or acquisitions (see Section 6.9 of the Registration Document for more details). These competitors have resources well above those of the Group and, in particular:

- larger budgets for research and development, clinical studies, marketing of their products and protection of their intellectual property;
- greater experience in obtaining and maintaining regulatory approvals for their products and improvements to existing products;
- more established distribution networks;
- greater experience and more resources in terms of launching, promoting, marketing and distributing products;
- more established infrastructure; and
- a stronger reputation.

In addition, the significant growth of the digital healthcare products market and its strong development potential are attracting new players looking for growth drivers, whether they are companies specialising in medical devices (such as Roche or Medtronic) or major digital players (such as Google). These major players also attempt to contribute to the building of an ecosystem, notably by establishing partnerships (Glooko-Medtronic), equity participation or acquisitions (Roche-MySugr). The arrival of these new players with solid know-how and significant financial strength encourages companies already present in this market to step up their competitive efforts.

Although the Group considers that it has significant competitive advantages particularly due to its original therapeutic positioning or its Theraxium technological platform, this does not guarantee that competitors will not develop therapeutic, or other competing or alternative solutions over the same period or later, making those currently developed or preferred by the paying bodies, physicians or patients less attractive or obsolete (see Section 4.1.1 of the Registration Document for more details).

In addition to its intellectual property protection policy (see Section 11.3 of the Registration Document) and in order to preserve its technological leadership, the Group puts significant efforts into improving its existing products and developing new solutions adapted to new therapeutic indications. At 31 December 2018, the Group's R&D Department had 60 employees split between the development and industrialisation of the Group's products. The Group has also established strategic partnerships with major players in healthcare and technologies to treat various pathologies (such as diabetes or oncology with Sanofi (Diabeo and Insulia), AstraZeneca (Eco) and Abbvie (development of a solution in immunology respectively).

4.1.4 Risks related to the economic and financial environment

Although the healthcare sector is less sensitive to economic cycles, less favourable economic and financial conditions could affect the Group's operations and financial performances.

For example, the burden of state debt, rising unemployment, and declining numbers of individuals with private health insurance could put significant pressure on economic activity in the public and private sectors, leading to lower demand for the services that the Group offers to its customers, thus having an adverse effect on its operations.

Moreover, the debt reduction measures that governments might take, as was the case in Europe, would increase the pressure on the reimbursement rates for the Group's products (see Section 4.1.3. of the Registration Document for further details) as well as on the tax burden and, as a result, may disrupt the operating balance of the Group's activities.

The occurrence of one of these risks could have a material negative impact on the Group, its business, financial situation, results, development or prospects.

4.2 Risks related to the Group's business

4.2.1 Risks related to the partnership agreements necessary for the development and/or marketing of the Group's products

The Group's strategy is partially based on the development and/or marketing of its products in close collaboration with its major partners from the pharmaceutical sector (notably Sanofi, AstraZeneca and Abbvie) and the new technologies sector (notably Google via Verily). The mobilisation of its partners, especially in terms of expertise or human or financial resources, is not only crucial to develop and commercialise the Group's therapeutic software that is under development, but also to market those that are already approved.

The Group could suffer from the sluggishness, failure or competitive attitudes of its partners. Any failure on their part could have unfavourable consequences for the Group, its development and prospects.

Moreover, the Group and the partner could decide to unilaterally or jointly terminate the partnership agreement. Such a termination would lead to a delay in the development and marketing of the Group's products and would require it to seek a new partner. The Group cannot guarantee that it would then be able to enter into an agreement with a comparable partner or under similar economic conditions. Finally, the Group could be forced to increase its own R&D, marketing and sales capacity. It cannot guarantee that it will be able to commit the necessary financial and human resources to implement new skills and have the necessary time to put in place the appropriate organisation and structure.

The Group is also developing therapeutic software using its own funds. With regard to these products, the Group cannot guarantee that it will be able to conclude partnership agreements under satisfactory terms in order to be able to continue or accelerate the development of these products over time and at an acceptable cost, or to market them in all countries with sales potential.

The occurrence of one of these risks could have a material negative impact on the Group, its business, financial situation, results, development or prospects.

4.2.2 Risks related to the market launch of the Group's products and their marketing

4.2.2.1 *The Group's development will partly depend on the pace of adoption by healthcare professionals and patients of its products.*

Even if the Group and/or one or more of its business partners obtain the marketing authorisation allowing them to sell the medical devices developed by the Group, the latter cannot guarantee that they will obtain the support of the medical community, prescribers, patients and third-party payers. Acceptance by the market will thus depend on several factors, including:

- healthcare professionals may not recognise the therapeutic benefits of the Group's products or prefer potential competing and/or alternative products;
- healthcare providers may not adopt the Group's products due to lack of financial incentive mechanisms or integration into their IT organisation;

- patients themselves may not recognise the therapeutic benefits or prefer potential competing and/or alternative products;
- the practitioners' fear of risking liability through the use of new technology;
- the Group's competitors could develop one or more products for the same indication; and
- the cost of the solutions offered by the Group and the level of reimbursement of these products could also limit their acceptance by the market.

Although the Group believes that the software it is developing is likely to provide a therapeutic response to a need that has not been met to date, poor market penetration, as a result of one or more of the factors described above, would have a negative impact on their sales and on the Group's ability to generate profits through direct sales, but also under agreements entered into with industrial partners (such as Sanofi, Roche Pharma or AstraZeneca - see Chapter 22 of the Registration Document), which would have a negative impact on its activity, prospects, financial situation, results and development.

4.2.2.2 The Group has limited experience in marketing its products and cannot guarantee that it will be able to effectively market the products it develops.

The Group's development and ability to generate revenue will partly depend on its ability to market its products on a large scale and in new markets. The Group's sales strategy combines direct sales forces for paying and indirect bodies, notably through the conclusion of distribution partnerships with market players (such as Sanofi, Roche Pharma or AstraZeneca - see Chapter 22 of the Registration Document).

However, despite the experience of its managers, the Group still has limited experience in the areas of marketing and selling digital therapeutics, which represent a new industrial sector. In addition, the size of the Group's sales force remains small compared to the various players in the pharmaceutical market.

The success of marketing the products developed by the Group to third party payers will therefore depend in particular on its ability to develop a marketing strategy, as well as attract, recruit and retain a qualified sales force.

The successful marketing of the Group's products developed in partnership with pharmaceutical companies will depend on the marketing and commercial efforts of these partners as well as their ability to sell the therapeutic solutions developed by the Group (see Section 4.2.1 of the Registration Document for further details). Although the Group has entered into an agreement with a third-party payer (WellDyneRx) for the reimbursement of Insulia in line with normal commercial practices, it cannot guarantee that its sales forces will be able to conclude similar commercial agreements with other third-party payers in the future.

The occurrence of one or more of these risks could have a material negative impact on the Group's business, financial situation, results or development.

4.2.2.3 The Group may even have to withdraw from sale one or more of its products because of the unanticipated consequences of their use.

In the absence of adequate training, practitioners and patients may use the software developed by the Group and related services inappropriately or ineffectively. Misuse of a product could limit or even eliminate its therapeutic efficacy, cause discontent among patients, healthcare establishments and third-party payers, or even cause bodily injuries.

Such situations could undermine the Group's image and, in certain cases, could lead to amicable or judicial proceedings against it (see Section 4.3.2 of the Registration Document for further details). The Group may even have to withdraw, temporarily or permanently, from sale one of its products, at its own initiative or at the request of the competent authorities.

The occurrence of one of these risks could have a negative impact on the Group's business, prospects, financial situation, results and its development.

4.2.3 Risks related to the Group's customers

4.2.3.1 The market in which the Group operates is marked by the presence of major customers with significant market share and bargaining power.

The Group's commercial strategy aims to market its products, either through partnerships (notably with major pharmaceutical companies), or directly to public (such as state health insurance in France) or private players.

The Group's partners are well-established players in the market and have significant financial and human resources and, as a result, considerable bargaining power. Although the Group has entered into an agreement with a third-party payer (WellDyneRx) for the reimbursement of Insulia in line with normal commercial practices, it cannot guarantee that it will be able to enter into partnership agreements that will be favourable to it.

Payers also have a very significant bargaining power, based on the number of patients they represent, all the more so when it comes to public institutions. The Group cannot therefore guarantee that it will be able to market its products under the most favourable conditions, particularly financial conditions.

In addition, as the Group is in the development phase and although its strategy is to diversify its offering as well as the number of its customers, at the date of the Registration Document, the Group's sales were concentrated on a limited number of customers. One of these customers may not comply with its obligations towards the Group (see Section 4.2.6.2 of the Registration Document) or may decide to unilaterally terminate the contractual relations that bind it to the Group (see Section 4.2.1 of the Registration Document).

The occurrence of one of these risks could have a negative impact on the Group's business, prospects, financial situation, results and its development.

4.2.3.2 Some of the Group's customers may be facing insolvency problems.

The Group's strategy is to reach out, on the one hand, to major industrial players in the life sciences sector and, on the other hand, to private and public payers and healthcare providers.

Like the payers, large industrial healthcare providers have significant financial resources. Healthcare institutions (hospitals and clinics) operate essentially based on budgets. However, in certain territories, which are currently not targeted by the Group, financial risks may weigh on the payers and affect their capacity to honour the reimbursement of healthcare products.

For the years ended 31 December 2017 and 2018, no impairment charge has been recorded due to the absence of risk identified by the Company. Except in exceptional cases, the settlement period granted does not exceed 60 days.

For these reasons, the Group believes that it has low exposure to insolvency problems with its customers.

However, if one or more of the Group's customers are unable to meet their financial obligations, this could have a material negative impact on the Group's financial position and results, and therefore on its business, prospects and development.

4.2.4 Risks related to the Group's technology

4.2.4.1 The various products of the Group are based on a single technological platform.

The software developed by the Group or under development is based on the same Theraxium technology platform. This infrastructure platform includes features common to all add-ons (algorithmic components, user interface components, security components, etc.). This pooling makes it possible to develop companion solution faster, according to the existing quality processes for medical devices. In addition, the Theraxium platform also operates data flows and ensures the technical operation of the companion solution.

The use of one of these therapeutic software programmes, in a clinical setting or in real life, could reveal security problems related to the platform. These difficulties may require further R&D efforts to address them. Furthermore, they could question the development of the Group's products or the very functioning of the Theraxium technology platform. Finally, such events could result in the suspension and withdrawal of marketing approvals that the Group has obtained and delay or even prevent future approvals. Such a situation would have a material negative impact on the Group's business, its prospects, development, financial situation and results.

4.2.4.2 Access to the Group's products could be significantly restricted due to technical faults or malicious actions.

The Group provides its services via an integrated network. It has faced cyber-attacks in the past, which did not have a material impact to the Company's knowledge, and could face further attacks in the future, aimed in particular at disrupting its services, accessing its network, stealing technology or hacking data from its customers. The Group's services could also be disrupted due to technical faults.

Any disruption in access to the Group's network and systems due to a cyber-attack or technical fault could lead to the suspension or discontinuation of the Group's software and services or, if these faults were recurrent, their partial or total prohibition by competent regulatory authorities. These malfunctions could adversely affect the Group's brand image and commercial reputation, leading to a loss of customers, but also the Group's liability (see Section 4.3.2 of the Registration Document).

The Group may also incur additional costs to repair its network, correct a technical fault and improve the safety of its products, without guaranteeing the effectiveness of such repairs, corrections or improvements.

Such malfunctions could have a material negative impact on the Group's business, its prospects, development, financial situation and results.

4.2.4.3 The deterioration, inefficacy or lack of reliability of the mobile or internet networks could restrict or even prevent access to the Group's products.

The Group depends on the availability of reliable and economical internet and mobile networks on the markets where it provides its services through its software to patients and practitioners. In the event that the internet and/or mobile services in one or more markets in which the Group operates were slowed down or interrupted for any reason whatsoever (in particular in case of damage to infrastructure, adverse weather conditions, natural disasters, terrorist attacks, power cuts or legal or regulatory changes), the Group's products may no longer be commercially viable in such market(s).

In addition, the Group's geographic expansion could be limited by territories in which these internet and mobile networks are unreliable and the related infrastructure is not well developed. If the network infrastructure necessary for the provision of the services offered by the Group on a market is not developed or maintained, it would be impossible for it to gain access to this market and, where applicable, to remain there.

The occurrence of one of these risks could have a negative impact on the Group's business, prospects, financial situation, results and its development.

4.2.4.4 The availability of the Group's products depends on the availability and conditions of access to "stores" notably Apple and Android.

The Group's products are distributed via app stores managed by third parties, such as Apple's App Store or Google's Google Play. Its products are then subject to an application developer licence agreement. One or more of the main app store operators could refuse to distribute the Group's products through their store or decide to unilaterally amend the licence agreement in such a way that it would prohibit the Group from distributing its products. Such events could significantly reduce the number of patients using the Group's products and therefore its revenues.

Such events could have a negative impact on the Group's business, its prospects, financial situation, results and development.

4.2.5 Risks related to clinical trials, to which the Group submits its products at its own initiative

The Group develops its products in close collaboration with its partners and healthcare professionals in order to best meet their expectations and those of their patients. The Group also carries out numerous user trials on its products in the R&D phase, either internally or with subcontractors, in order to improve the operation of the software it develops.

Furthermore, in order to market a product for a given indication and territory, the Group is required to obtain the appropriate regulatory approvals for that product and in that territory (see Section 4.3.3.2 of the Registration Document), including the EC marking within the European Union or FDA approval in the United States. In this context, in addition to providing proof of the harmlessness of its products, the Group voluntarily carries out clinical studies on each of them in close collaboration with healthcare professionals to demonstrate their therapeutic benefit.

Any failure during one of the different test phases for a given indication could delay the development and marketing of the software concerned or even stop its development. In addition, the Group may not obtain the regulatory approvals necessary to market its products in the countries concerned. Lastly, if a clinical study on a product fails after obtaining the required regulatory approvals, it might jeopardise the marketing of this product in all or part of the targeted territories.

The occurrence of one of these risks could have a negative impact on the Group's business, prospects, financial situation, results and its development.

4.2.6 Risks related to the Group's IT service providers

The proper functioning of the products developed by the Group depends on certain services provided by IT service providers (including hosting the bulk of the development infrastructure and solutions under production, the maintenance and security of its servers, access to the distribution network or the programming and maintenance of its software and operating systems).

The services provided by these third parties could malfunction or even be abruptly interrupted. Their infrastructure could also be inaccessible for a short or long period. One of these failures could lead to an impairment or even the suspension of the operation of the Group's products. The latter cannot guarantee that its suppliers will then be able to resolve these disruptions within a reasonable period of time.

In addition, although the Group strives as much as possible not to be dependent on its suppliers, if these third parties no longer wished or were no longer able to provide their services to the Group, it would then have to switch suppliers, which could lead to the immobilisation of technical and financial resources necessary for the development of the Group's other projects.

Finally, these malfunctions could adversely affect the Group's brand image and commercial reputation, leading to a loss of customers, but also the Group's liability (see Section 4.3.2 of the Registration Document).

The occurrence of one of these risks could have a negative impact on the Group's business, prospects, financial situation, results and its development.

4.3 Legal and regulatory risks

The Group manages the legal aspects and compliance with the regulatory framework internally (marketing approvals, insurance, intellectual property, trademarks and domain name applications, etc.). In this respect, the Group may use intermediaries, service providers or specialised advisers to supplement its expertise, or outsource certain tasks to them. Thus, the Group uses an industrial property consultant working closely with its research and development team, quality assurance and regulatory affairs consultants, and more occasionally, specialised lawyers, insurance agents, consultants and local regulatory representatives for the submission of certification files to certain local regulatory authorities.

4.3.1 Risks related to various regulatory frameworks

4.3.1.1 Risks related to the gathering and use of personal data.

As a rule, the Group collect and retains personal data, particularly relating to the health of the users of its software solutions. However, in some cases, the Group's industrial partners themselves host the software solutions that it develops. On the date of the Registration Document, the data which the Group is responsible for hosting is hosted in France and the USA on separate servers operated by separate, approved health data hosts. In this respect, the Group does not transfer personal data between the servers located in the USA and those located in France. These approved hosts are responsible for the maintenance and safety of these servers, in accordance with the local regulation applicable for the protection of personal and health data.

Within the European Union, the processing of personal data carried out by the Group is, on the one hand, subject to the provisions of the general regulation on data protection (EU) 2016/679 (applicable from 25 May 2018) and the French Law No. 78-17 dated 6 January 1978 on data privacy and, on the other hand, likely to be subject to the regulations as per the French Code of Public Health. These laws and regulations set forth obligations relating to the legality of the processing, the obligatory information to be delivered to the persons concerned by the processing and the technical and organisational security measures intended to ensure a level of security adapted to the risks generated by the processing. Non-compliance with these requirements could lead to administrative fines as well as civil or criminal penalties.

In the USA, several federal and local laws protect the confidentiality of the information about some patients' health condition, especially medical files, and reduce the use and disclosure of such protected information. The US Department of Health and Human Services promulgated rules concerning patient privacy pursuant to the 1996 Act (Health Insurance Portability and Accountability Act - US). Department of Health and Human Services -HIPAA). These rules protect medical records and other health information by limiting their use and disclosure, giving individuals the right to access, rectify and track their own medical data, and by limiting most uses and disclosures of health information to the minimum that is reasonably necessary to achieve the intended purpose. The violation of confidentiality rules and patient safety under the HIPAA law or the violation of the Group's protection measures relating to personal data covered by the HIPAA law could lead to civil or criminal penalties.

Although the subcontractors used by the Group are selected after an evaluation and in-depth discussions for the performance and quality of their services, the Group cannot guarantee that they will always be able to comply with the local regulations applicable to the protection of personal and medical data.

Moreover, even if the Group has implemented measures to protect and secure personal data collected using its technology, it cannot be ruled out that the databases and data collected and used by the Group might be the target of piracy, virus, theft, fraudulent use or destruction or other unauthorised uses of personal data (see Section 4.2.3 of the Registration Document for further details). As a result, the Group could be held liable or its public image could be very significantly affected, which would have a material negative impact on the Group, its business, financial position, results, development and prospects.

4.3.1.2 The medical devices developed by the Group are covered by specific regulations that are likely to change.

The marketing of the Group's products in Europe requires the EC marking to be obtained.

The Group's products meet the definition of medical devices and are governed, among others, by the provisions of the amended European Directive 93/42/CEE which harmonises the conditions for the sale and free circulation of the Group's products within the European Economic Area.

These products can be launched on the market only after obtaining certificates that permit the EC marking, and are valid for a limited period. This EC marking is proof of compliance of the relevant medical device with the essential health and safety requirements set out by the applicable European directive and attests that it has undergone adequate procedures for assessing its compliance.

Further information on the European legislation applicable to the Group's products can be found in Section 6.5 of the Registration Document.

If some of the Group's products have already obtained the EC marking, the products under development will be subject to this same regulation. In the event of failure in obtaining the certificates allowing EC marking within the prescribed time, the market launch of these products could be delayed or even abandoned.

Furthermore, applications for the renewal of the EC marking certificates require, among other things, maintenance of compliance of the quality system, consideration of regulatory changes, update of risk management and compliance with the essential requirements of the applicable European directives.

If the Group fails to obtain the renewal of the certificates necessary for the EC marking of its products within the required deadlines, their marketing could be interrupted until these authorisations are obtained, or even rejected.

Such situations, if they do occur, could have a material negative impact on the Group, its business, financial position, results, development or prospects.

The marketing of the Group's products in the United States requires prior authorisation of the FDA.

The US market is governed by the federal regulation Title 21 of the US Code of Federal Regulation (CFR), which regulates the market launch of medical devices by imposing pre- and post-marketing requirements for which the control body is the Food and Drug Administration (FDA).

These medical devices are also subject to registration of the establishment manufacturing medical equipment under subsections B, C and D of Section 807 of Title 21 of the CFR. The FDA issues a 510 (k) licence, if it is proven in the application for authorisation that the medical device is largely equivalent to one or more medical devices already approved on the US market, i.e. the medical device subject of the application for authorisation is at least as safe and effective as previously authorised product(s).

Information on the manufacturer, the initial importer and the medical device appear on the FDA's computer databases in lists of licensed medical devices and the register of establishments manufacturing medical equipment.

Further information on the US legislation applicable to the Group's products can be found in Section 6.4 of the Registration Document.

Although the Group communicates with the FDA to give more details about the regulatory approval path for some of its products in the United States (such as those related to oncology), it cannot guarantee the outcome of these discussions. If the US marketing authorisation applications for the Group's products were to be rejected by the FDA, the marketing of these products on the US market would have to be delayed until new applications for authorisation have been approved, or even rejected. Similarly, if the FDA's authorisations already obtained for some of the Group's products were successfully challenged, this would lead to their withdrawal and the Group would no longer be able to market the products concerned on the American market until they obtain new authorisations. In each of these cases, the FDA may be able to conduct other types of longer, more complex, and more expensive tests that may require clinical reporting.

Such situations, if they do occur, could have a material negative impact on the Group, its business, financial position, results, development or prospects.

Specific steps may be necessary to market the Group's products in other countries.

In addition to the specific rules in Europe and the United States, the market launch of medical products in other countries requires specific steps to obtain the necessary authorisations (especially in Japan, China, Brazil, etc.).

However, there are certification equivalents and recognitions in some countries (notably in Canada, Singapore or Australia). These equivalents or recognitions are important elements in the process of making the decision to market the products developed by the Group in a new country.

If requests for authorisations for Group products were to be rejected by a public authority, or if the authorisations granted were cancelled as a result of appeal (ex gratia or contentious) by third parties, the Group could not market its products on the relevant market or may have to implement other, longer and more expensive procedures to obtain its authorisations, or, if the Group does not obtain any authorisation in any territory, it may not be able to market its products.

Such a situation could have a material negative impact on the Group, its business, financial situation, results, development or prospects.

4.3.2 Risks invoking liability on account of the products

Apart from legal guarantees, the Group could be exposed to liability risks on account of the products it develops.

Its liability could therefore be engaged by patients participating in clinical trials as part of the development of the software tested, due particularly to any unexpected adverse effects resulting from the use of these software programmes or more or less serious complications related to a software malfunction (e.g.: in case of a very high insulin dose recommended by this software).

The Group's liability could also be engaged in the marketing phase of its products. Civil or criminal proceedings may be initiated against the Group by patients, practitioners, the relevant regulatory bodies, its industrial partners and payers and/or any other third party using or marketing the Group's products. Such actions may include claims resulting from acts of the Group's partners, licence holders and sub-contractors over which the former has no or little control.

The malfunction of the products marketed by the Group could also lead to expenses related to the replacement of the Group's products as well as new research and development expenses in order to review the design and operation of the defective products. Lastly, it could reduce or even monopolise the technical and financial resources needed to develop other Group projects. The existence of defective products could also adversely affect the Group's brand image and commercial reputation, leading to a loss of customers.

Moreover, although at the date of the Registration Document the Group has not been the subject of any action for liability or any other complaint related to the implementation of its technology or the use of its products, it cannot guarantee that its current insurance coverage (see Section 4.7 of the Registration Document) is sufficient to respond to actions that might be taken against it, or to respond to an unexpected situation.

If its liability or its partners, licence holders and sub-contractors' liability were challenged, if the Group or its partners, licence holders and sub-contractors were unable to obtain and maintain appropriate insurance cover at an acceptable cost or if the Group were unable to somehow guard against liability actions, it could seriously affect the marketing of its products and more generally adversely affect the Group's business, results, financial situation and development prospects.

4.3.3 Risks related to intellectual property

4.3.3.1 *The Group's patents and other intellectual property rights have uncertain or limited protection in terms of time.*

Intellectual property law varies from country to country and is constantly evolving, thus constituting a source of uncertainties. The success of the Group depends on its ability to obtain, preserve and protect its patents, trademarks, copyrights, designs, models and domain names but especially its other intellectual property rights or similar (such as its trade secrets, software, business secrets and its know-how, including the algorithms created by the Group) or those it is authorised to exploit in the course of its activities. The development and marketing of the technology or product/service concerned could be directly affected or interrupted if one or more patents or trademarks covering a technology or a product/service of the Group were to be invalidated or deemed unenforceable, or if the Group's know-how was to be disclosed.

The Group's strategy is to patent specific features of the software it develops, within the limits permitted by the regulations of each country. Indeed, software is not as such protected by patent law, since the protection of the source code or software architecture is protected by copyright, provided that the software constitutes a creation unique to its author.

That being said, as of the date of the Registration Document, patents that the Group considers useful for its activity have been issued or have been the subject of a patent application. However, there can be no assurance that these will not be challenged, invalidated or circumvented or that they will provide effective protection against competition and third party patents that would cover similar compositions, processes or products. The absence of sufficiently extensive protection, invalidation or circumvention of patents could have material negative effects on the Group.

The same goes for software; with competitors able, to a certain extent and under certain conditions, to independently build software that fulfils similar functionalities that compete with the Group's and its partners' own software.

In addition, the Group's success will depend on its ability to develop new products or technologies that do not infringe patents or other proprietary rights belonging to third parties. Despite the trademark searches and the monitoring it carries out, the Group cannot be certain that it does not infringe industrial property rights, even if the Group holds a patent or has filed a patent application relating to the products or technologies developed by the Group. Indeed, the Group cannot be certain of being the first to file a patent application. In fact, at the time of filing a patent application, other patents or patent applications may constitute opposable but not yet published prior registrations or, even if published, may not be known to the Group. It should be noted that the publication of patent applications takes place 18 months after the applications have been filed. In addition, a patent application or granted patent does not confer an approval to exploit the product or technology it covers. Thus, products or technologies developed by the Group, while being protected by a patent application or a patent, may infringe industrial property titles held by third parties on specific elements of the technology.

Similarly, when registering one of its trademarks or when registering a domain name in a country where these rights are not covered, the Group may find that the trademark or domain name in question is not available in this country. A new trademark or domain name would then need to be found for the given country or an agreement negotiated with the holder of the previous mark.

In addition, the fact that trademarks have already been registered in some countries does not rule out the risk of third party claims or actions instituted before competent offices and/or courts, which could undermine the validity of acquired rights.

There is therefore no certainty that the Group's current and future applications for patents, trademarks and other intellectual property rights will be subject to issuance/registration and that such rights will be effectively protected, or that acquired rights will not be questioned or cancelled.

In this respect, it should be emphasised that copyright cannot be the subject of searches since the right arises from the date of creation without the formalities of filing. There is therefore no register of existing creations that could potentially constitute relevant prior registrations. Likewise, the risks in the field of unfair and/or parasitic competition are difficult to assess.

The effective protection of software before the courts can be more or less difficult from one jurisdiction to another. Therefore, the Group cannot guarantee that it will be able to systematically pursue third parties who market or exploit similar software.

The Group intends to pursue its patent protection policy by filing new applications as and when it deems appropriate, and by pre-constituting evidence of its software creation. In particular, the Group intends to pursue its policy of protecting the specific patent formulations that it develops.

However, it cannot be ruled out that:

- the Group may fail to develop new patentable inventions or may face difficulties in filing and reviewing some of its applications for future patents, trademarks or other industrial property rights. Indeed, the filing of a patent application or trademark does not in any way preclude the actual obtaining of a title or reduce the scope of the title obtained during the review. Moreover, the filing of an application for a patent or trademark or the grant of a patent or trademark by an office does not in any way preclude the obtaining of a patent/trademark, even of similar scope, from another office;
- or that the Group's intellectual property rights might be contested and considered invalid or that the Group is unable to enforce them. The issuance of a patent, trademark or other industrial property rights, as well as the filing of a source code, does not guarantee the validity or enforceability, as third parties may question both aspects. Actions in court or at the competent offices and/or courts may be necessary to enforce the Group's intellectual property rights, protect its trade secrets and know-how or determine the validity and extent of its intellectual property rights. Any dispute could result in considerable expenses, negatively impact the Group's results and financial situation and image and not provide the protection sought. The Group's competitors or any third party with an interest in acting could successfully challenge the validity of its patents or trademarks in court or in other proceedings. This could reduce the scope of these patents or trademarks, or even cancel them, and allow competitors to circumvent them. As a result, the Group's rights to patents granted and/or trademarks filed and/or registered may not provide the expected protection against competition;
- there are trademark rights, copyrights, in particular on software, or other prior third party rights that could provide a base for infringement or liability proceedings (including unfair competition) against the Group;
- the extent of patent protection is insufficient to protect the Group against the risks associated with counterfeiting or competition. The question of the patentability of medical devices and software is very complex and raises legal, scientific and factual issues. There are general trends to standardise the approach to the patentability of pharmaceutical inventions by the three major patent offices worldwide in the United States, Europe and Japan. Nevertheless, there are still uncertainties regarding the interpretation of the scope of patent claims, which is a matter of national law. Developments or changes in the interpretation of intellectual property laws in Europe, the United States or other countries could change the Group's legal situation and positioning against its competitors. In addition, some countries do not protect intellectual property

rights as efficiently (lack of common regulations or harmonisation) as in Europe or the United States.

- third parties claim rights to patents, know-how or other intellectual property rights owned by the Group, or on which it may benefit from a licence. The Group's collaborations, partnerships, service contracts or outsourcing contracts with third parties expose it to the risk of third parties claiming the benefit of intellectual property rights over the Group's inventions or failing to ensure confidentiality of the Group's innovations, source codes, or non-patented improvements and know-how. In addition, the Group may provide, in various forms, data or information to third parties with which it collaborates (such as academic institutions and other public or private entities) concerning the research, development and marketing of its products.
- partners, including scientists, with whom the Group has entered into cooperation involving intellectual property rights, some of which are held by these partners, are unable to fulfil their contractual obligations, or continue their collaboration with the Group. The latter may itself be required to put an end to or revise the conditions of collaboration with these partners. These different scenarios could have a material impact on the development and/or marketing operations of some of the Group's products/services.

Despite the precautions, including contractual, taken by the Group with these entities, they could claim the ownership of intellectual property rights resulting from tests carried out by their employees. In the case of co-ownership of intellectual property rights, these entities may not grant exclusive operating rights to the Group, in a manner that is acceptable to the latter.

4.3.3.2 Intellectual property rights held by the Group or by third parties could be subject to a dispute, the outcome of which would be uncertain.

Disputes relating to intellectual property are often long, expensive and complex. Some of the Group's competitors have more significant resources and therefore have greater ability to conduct such proceedings. An unfavourable legal decision could seriously affect the Group's capacity to pursue its activity, and more precisely, could compel the Group to:

- stop selling or using some of its products, software or technologies;
- acquire the right to use third party intellectual property rights under on unfavourable terms; or
- redesign some of its products/technologies or, in the case of trademark claims, rename its products so as to avoid infringing third party intellectual property rights, which could prove long and expensive, and could affect the efforts of the Group and/or its partners to market the products.

Group competitors or any third party with an interest in doing so could successfully challenge the validity of its patents or trademarks, the originality of the software, or other intellectual property rights in court or as part of other proceedings, which, depending on the outcome of such disputes, could reduce their scope, result in their invalidity or allow competitors to circumvent them. As a result, the Group's rights on its patents, trademarks or other intellectual property rights might not grant the expected protection against competition.

4.3.3.3 The Group cannot guarantee protection of the information and know-how that it communicates to its partners.

The Group considers it essential to guard against the unauthorised use and disclosure of its confidential information, source codes, know-how and trade secrets. In fact, non-patented and/or non-patentable technologies, procedures, methods, know-how and data are considered as trade secrets that the Group tries to protect in part by means of confidentiality agreements.

Various types of information and/or products may be entrusted to them in order to carry out certain tests and trials, as part of collaboration, partnership, research or other type of cooperation agreements entered into by the Group and consultants, partners, sub-contractors, or any co-contracting third party. In such cases, the Group requires confidentiality agreements to be signed. Furthermore, as a rule, the Group ensures that the collaboration or research contracts that it signs give it access to full or co-ownership of the results and/or inventions resulting from this collaboration or to an exclusive licence for such results and/or inventions. However, as an exception, the Group has entered into certain agreements under which the patents and know-how developed will, in a specific field, be exclusively held by the other party.

It cannot be ruled out that the agreements put in place to protect the Group's technology and trade secrets and/or the know-how put in place do not provide the protection sought or are violated, that the Group does not have any appropriate solutions against such violations, whether its trade secrets are disclosed to its competitors or developed independently by them, especially as some of the Group's partners may, in the longer or shorter term, compete with the Group. As part of the agreements entered into with third parties, the Group sometimes takes the precaution of specifying that the latter are not authorised to use the services of third parties or that they can only do so with the prior approval of the Group. However, the fact it cannot be excluded that some of its co-contracting parties still resort to third parties. In this case, the Group has no control over the conditions, under which the third parties with whom it contracts, protect its confidential information, regardless of whether the Group provides in its agreements with its co-contracting parties that they undertake to pass on these confidentiality obligations to their own co-contracting parties.

Thus, such agreements expose the Group to the risk of seeing the relevant third parties (i) claiming the benefit of intellectual property rights over the Group's inventions, software, or other intellectual property rights, (ii) failing to ensure the confidentiality of non-patented innovations or improvements to the Group's confidential information and know-how, (iii)) disclosing the Group's trade secrets to its competitors or developing these trade secrets independently and/or (iv) violating such agreements, without the Group having an appropriate solution against such violations.

4.3.3.4 Some of the Group's intellectual property rights are pledged

In order to guarantee the repayment of bonds subscribed to by Kreos Capital V (UK) Ltd. ("Kreos") on 13 April 2018 (see Section 22.6 of the Registration Document), the Company granted Kreos a pledge on some of its assets and in particular on its intellectual property rights in France, Europe and the USA, its bank accounts and its receivables (for more details on these pledged intellectual property rights, see Section 11.6 of the Registration Document). If the Company fails to pay for bonds subscribed to by Kreos or declare the early repayment of the bonds subscribed to by Kreos following the occurrence of a default event provided for in the bond issue agreement, Kreos may acquire ownership of the pledged intellectual property rights.

In the event of such a transfer of ownership, the Group's ability to license and develop its products covered by these intellectual property rights could be affected or delayed, which would consequently have a material negative impact on the Group's business, prospects, ability to achieve its objectives, financial position, cash flow or operating income.

4.3.4 [Risks related to statutory audits](#)

The French agency for the safety of medicines and health products (ANSM), the FDA and any other authorities periodically carry out audits to ensure that the Group applies the approved quality system, including the EC marking, FDA approval or any other marketing authorisations.

If any of these regulatory authorities detects a critical non-conformity, they may suspend or withdraw the EC certificate or FDA approval after formal notice to the Group to achieve compliance has gone unheeded.

The occurrence of such an event could jeopardise the marketing of the Group's products in the countries concerned and, consequently, significantly affect the Group's business, financial position, results, development and medium and long-term prospects.

4.4 Risks related to the Group organisation and development strategy

4.4.1 [Risks related to the implementation of the Group strategy](#)

The Group has positioned itself in the digital healthcare applications market, which, despite strong growth, remains a very young market. The Group has also decided to focus its efforts on indications wherein it believes to be in a position to fulfil needs that have not been met to date.

Furthermore, the Group is currently marketing its products through partnerships with large-scale healthcare companies so as to benefit from their networks with paying bodies, practitioners and healthcare establishments. In view of the characteristics of the market in which it operates, the Group wishes to be able to contact the paying bodies and healthcare providers directly and make the necessary investments to be able to do so.

Further information on the assumptions made to characterise the markets targeted by the Group and to define its marketing strategy can be found in Sections 6.1 and 6.8 of the Registration Document.

The Group cannot guarantee that these assumptions will be confirmed. Failure to implement all or part of these assumptions could significantly affect the Group's business, financial position, results, development and medium and long-term prospects.

4.4.2 [Risks related to the management of the Group's internal growth](#)

As part of its development strategy, the Group will need to recruit additional staff and develop its operational capacities in line with its development and commercial prospects, which could mobilise impose excessive strain on its internal resources.

The Group intends to reinforce its direct sales force to market its products, especially in the USA. Besides the direct costs associated with the development of its sales force.

In order to do so, the Group must:

- train, manage, incentive and retain a growing number of employees;

- anticipate new expenses associated with this growth and corresponding financing requirements;
- forecast as accurately as possible the demand for its products and the revenues they can generate;
- increase the capacity of its existing operational, financial and management IT systems; and
- manage relations with the Group's partners responsible for the continued development and marketing of its products.

If the Group is unable to manage this growth or if it faces unexpected difficulties during its expansion, it could have a material negative impact on its business, financial situation, results or development.

4.4.3 Risks related to the dependence on qualified personnel and key management personnel and the inability to attract new employees that the Group will need for its development

The success of the Group depends largely on the work and expertise of its senior executives and qualified staff. Although the Group has entered into so-called "key person" insurance for some of its senior executives, the temporary or permanent unavailability of one or more of these individuals or other key employees of the Group could lead to:

- loss of know-how and the weakening of certain businesses, all the more so in the case of transfer to competition; or
- shortcomings in terms of technical skills that may slow down the business and may ultimately affect the Group's ability to achieve its objectives.

Furthermore, the Group will need to recruit new executives and sales staff and qualified scientific personnel for the development of its business. It is in competition with other companies, research bodies and academic institutions, particularly to recruit and retain highly qualified scientific, technical and management personnel. If this competition is very intense, the Group would not be able to attract or retain these key personnel under conditions that are acceptable from a financial point of view.

The Group's inability to attract and retain these key persons could prevent it from achieving its overall objectives, especially in the United States, and therefore have a material negative impact on its business, results, financial situation, development and prospects.

Faced with this risk, the Group has set up contractual arrangements specific to its business and compliant with labour laws: non-compete provisions, non-poaching, transfer of intellectual property and confidentiality. It has also set up an incentive and retention policy in the form of performance-based variable compensation and the award of financial instruments giving access to the Company's share capital.

4.4.4 Risks related to the possible realisation of external growth operations

The Group may have to acquire new (commercial or technological) assets or companies in future. The Group cannot guarantee that it will be able to identify the best opportunities and realise these acquisitions, or that it will be able to successfully consolidate these acquisitions.

In addition, these acquisitions could impose significant costs on the Group. The Group may also have to finance such acquisitions by borrowing, or issuing equity securities, which could cause it to take financial risks and be subject to certain restrictions or have a dilutive impact on its shareholders.

The Group's business, financial situation, results, development and prospects could be significantly affected by the occurrence of one or more of these risks.

4.5 Financial risks

The accounting data mentioned in this section are derived from the consolidated financial statements presented under IFRS for the financial year 2017, included in Section 20.1 of the Registration Document.

4.5.1 [Liquidity risk](#)

Since its creation in 2001, the Group has recorded operating losses. As at 31 December 2018, cumulative net losses amounted to €53,774 k, compared to a cumulative net loss of €37,360 k at 31 December 2017. These losses result in particular from research and development and sales and marketing expenses incurred.

The Group has primarily financed its growth through capital increases and additional funds from research collaborations and research tax credits.

Thus, in 2009, the Company took a repayable advance for commercial prospecting in the United States from Coface. The total amount of this advance still owed at 31 December 2017, as it appears in the consolidated financial statements prepared under IFRS for the financial year ended 31 December 2017, featured in Section 20.1 of the Registration Document, is €170 k; This advance was fully repaid in March 2018.

In 2014, Voluntis contracted a financial loan of €850k. As this loan did not include an early repayment clause, the Company was not exposed to the liquidity risk that could result from the application of such a clause.

Under a Venture Loan Agreement and a Bond Issue Agreement entered into on 13 April 2018 between the Company and Kreos, on 1 May 2018, Kreos paid the nominal amount of €4 million corresponding to the first tranche of the bond issued by the Company. In addition, at the request of the Company, on 11 April 2019, Kreos subscribed two additional tranches of dry bonds for a total amount of €3 million, bringing the total amount of the bond issue to €7 million. For more information on the bond issue granted by Kreos, see Section 22.6 of the Registration Document.

In addition, as part of its initial public offering on the Euronext regulated market in Paris, the Company raised €30.1 million.

At the date of the Registration Document and given the funds received by the Company as described above, its cash position is approximately €16.2 million. The Company has conducted a special review of its liquidity risk and believes that it will be able to meet its future maturities over the next twelve months.

In any case, the Group will continue to have significant financing needs, as it continues to research and develop current and future products and support its commercial roll-out.

Financing needs are difficult to predict with precision and will depend in part on factors that are independent of the Group. Points showing major uncertainty include, but are not limited to:

- the costs and time required for product development and obtaining regulatory approvals in a context of increased regulatory requirements for manufacturing the Group's solutions;
- the need to obtain new approvals to accompany the marketing of the Group's products on new medical indications;
- the costs and time required so that the solutions developed by the Group are marketed and/or reimbursed to generate revenues;
- the balanced allocation of costs and revenues from business partnerships;
- the costs for preparing, filing, defending and retaining patents and other intellectual property rights;
- the competitive intensity and pace of adoption of new digital therapeutic solutions by players from the field of healthcare.

Furthermore, until now, a large portion of the Group's revenue was generated through upfront payments or milestone premiums under various partnerships that it has entered into. As a result, the Group cannot guarantee that it will become profitable, since achieving profitability implies that it must expedite the commercial roll-out of its diabetes management solutions (especially with third-party payers) or that it markets other products.

In this context, the increase in the Group's expenses without any correlation to an increase in its revenue could have a material negative impact on the Group, its business, financial situation, results, development and prospects. The Group may need to review its clinical and commercial development plan and should also look for alternative sources of financing.

If the Company raises equity by issuing new shares, the participation of its shareholders could be diluted. Financing through indebtedness, even if available, could also include restrictive conditions for the Company and its shareholders.

The realisation of this liquidity risk could have a material negative impact on the Company, its business, financial position, results, development and prospects.

4.5.2 Risks related to research tax credit

To finance its activities, the Group also opted for a Research Tax Credit (RTC), which consists of the government offering a tax credit to companies with major investments in research and development. Research expenses eligible for the RTC include, but are not limited to, salaries and wages, depreciation of research equipment, services outsourced to approved research organisations (public or private) and intellectual property costs.

For the years ended 31 December 2017 and 2018, the RTC recorded by the Company amounted to €1,682 k and €1,791 k respectively.

The Group cannot rule out the possibility that the tax authorities may question the methods used for calculating research and development expenses that it has selected even if the Group complies with the documentation and cost eligibility requirements or that the RTC may be questioned (for past or future years) by a change in the regulations. Such a situation could have a negative impact on the Group's results, financial situation and prospects.

4.5.3 [Dilution risk](#)

Since its inception, and as part of its policy to incentivise its corporate officers and employees, the Company has granted founders' stock options (BSPCEs), warrants (BSAs), stock options (Options) and free shares (AGAs).

In addition, in exchange for bonds issued by the Company in favour of Kreos (see Section 22.6 of the Registration Document for more details), the latter allocated to Kreos Capital V (Expert Fund) L.P. 70,000 warrants (BSA_{2018-Kreos}) giving the right to subscribe to 70,000 shares.

At 31 December 2018, the maximum potential dilution resulting from the exercise and final allocation of all dilutive instruments outstanding issued by the Company was 11% on the basis of the capital existing at the date of the Registration Document and approximately 10% based on diluted capital.

As part of its policy to incentivise its managers and employees and to attract complementary skills, the Company could, in future, issue or allocate new shares or new financial instruments giving access to the Company's capital, which would lead to additional, potentially significant, dilution for current and future shareholders of the Company.

4.5.4 [Risks related to indebtedness and restrictive financing clauses](#)

Under a Venture Loan Agreement and a Bond Issue Agreement entered into on 13 April 2018 between the Company and Kreos, on 1 May 2018, Kreos paid the nominal amount of €4 million corresponding to the first tranche of the bond issued by the Company. In addition, at the request of the Company, on 11 April 2019, Kreos subscribed two additional tranches of dry bonds for a total amount of €3 million, bringing the total amount of the bond issue to €7 million. For more information on the bond issue granted by Kreos, see Section 22.6 of the Registration Document.

The Venture Loan Agreement and Bond Issue Agreement require the Group to comply with certain commitments. These commitments on the part of the Group limit, inter alia, its ability to:

- take out any debt or grant guarantees;
- create security interests;
- pay dividends or other unauthorised payments; and
- sell, transfer or dispose of the assets necessary for its business.

These restrictions could affect the Group's ability to conduct business and limit its capacity to react depending on market conditions or even to seize commercial opportunities that may arise. In addition, the Group's ability to comply with these restrictive clauses could be affected by events beyond its control, such as economic or financial conditions.

Failure by the Group to comply with one of these commitments would allow Kreos to claim the early repayment of the loan granted.

Furthermore, to guarantee the repayment of these bonds, the Company granted a pledge on some of its assets (including receivables, bank accounts, and intellectual property rights).

This collateral may be implemented by Kreos in the event of the Company's default on payment or early repayment of the bonds due to the occurrence of any default event as stipulated in the issue agreement. Implementation of any of this collateral would result in a court order, a forced sale, or, as applicable, the transfer of ownership of the pledged asset in question to Kreos.

The realisation of one of these risks would have a material negative impact the Group's business, prospects, ability to achieve its objectives, financial position, cash flow or operating profit.

4.5.5 [Risks related to the future use of tax losses carried forward](#)

At 31 December 2018, after taking into account the net loss for the year, the Company has a tax loss carry forward of €56,377 k. As of the date of the Registration Document, this loss can be carried forward indefinitely against future profits.

In France, allocation of these losses is capped at €1 million, plus 50% of the fraction of profits in excess of that cap. The unused balance of the loss can be carried forward to subsequent years and is chargeable under the same conditions without any limitation in terms of time.

The possibility that future tax developments in the area of corporate taxation will call into question all or part of the allocation of these previous losses to future profits or limit it in time cannot be ruled out. For the coming years, France has also decided to gradually reduce the standard rate of corporation tax applicable to the taxable profits to which these losses could be charged.

The occurrence of one or more of these risks could have a material negative impact on the Group, its business, financial situation, results, development and prospects.

4.5.6 [Credit risk](#)

The Group manages its available cash carefully. Cash and cash equivalents include available cash and current financial instruments held by the Group. At 31 December 2018, cash and cash equivalents of €19,783 k were held in deposit accounts and fully available.

The credit risk related to cash, cash equivalents and current financial instruments is not significant given the quality of the financial institutions on which the Group relies.

Regarding the quality of its customers' signature, the Group has not identified any credit risk attached to the customer item.

4.6 Market risks

4.6.1 [Exchange rate risk](#)

A part of the Group's operating income is generated in currencies other than the euro. Due to the Group's geographic presence, the same is true for expenditures that are, for a growing part, denominated in foreign currencies, particularly in US dollars.

As at 31 December 2018, 99% of the Group's cash and other short-term financial assets were denominated in euros.

However, the Company considers that the change in USD/EUR exchange rates would not have a material impact on the Group's earnings and shareholders' equity (consolidated).

At its current stage of development, the Group has not taken any hedging measures, other than natural hedging, to protect its business against fluctuations in the euro/dollar exchange rate. The Group cannot exclude that a significant increase in its activity, particularly in the United States of America, could result in greater exposure to currency risk and would then consider using a suitable policy to hedge these risks.

4.6.2 [Interest rate risk](#)

Interest rate risk reflects the Group's exposure to fluctuations in interest rates in the market.

The bonds issued by the Company to Kreos (see Section 22.6 of the Registration Document) bear interest at a fixed rate and interest is payable on the final maturity date of said bonds. As a result, the Company does not consider itself to be exposed to interest rate risk for this bond issue.

The only exposure to interest rate risk relates to the investment of cash in cash equivalents consisting exclusively of term accounts. Given the current low level of remuneration of this type of investment and the level of cash amounts generally held by the Group, the latter believes that any change of +/- 1% would not have a material impact on its net income with respect to the losses generated by its ongoing operations. Furthermore, the Company's policy is not to subscribe to financial instruments for purposes of speculation.

The Group has no floating rate debt. Debt repayment flows are not subject to a risk of rate increases.

A description of the outstanding debt at 31 December 2018 is provided in Note 5.8 to the consolidated financial statements prepared for the year ended 31 December 2018 in Section 20.1 of the Registration Document.

4.7 Insurance and risk coverage

The Group has implemented a policy for covering its main insurable risks with amounts of cover that it considers compatible with its cash flows and business needs.

For the financial year ended 31 December 2018, the Company paid a total of €102 k in insurance premiums.

The Group holds several insurance policies, including the following:

Insurance policy	Risks covered	Insurance company or broker	Guarantee amount	Deductibles	Expiry
Product/professional civil liability, liability insurance for operations, legal defence	Professional civil liability: i) non-consequential non-material damage and professional liability ii) intellectual property iii) Privacy and communication costs Worldwide coverage	Chubb France	Product/Professional insurance coverage cap: - €10,000,000 per insurance period, including (i) €10,000,000 under Privacy guarantee (including USA/Canada) and (ii) €1,000,000 under intellectual property (including USA/Canada) Operating liability coverage limit: - €8,000,000 per insurance year, including €1,500,000 per claim for material and immaterial damage. Cap on professional legal recourse guarantees: €15,000 per insurance year and €2,000 per claim	Product/professional civil liability: - €15,000 per claim (€20,000 per Privacy claim) Liability insurance for operations: €3,000 per claim	Renewable every year on 1 January

Insurance policy	Risks covered	Insurance company or broker	Guarantee amount	Deductibles	Expiry
offices space risks - Suresnes (France)	Office space guarantee: i) damage to professional furniture and equipment ii) post-disaster costs and related financial losses iii) occupant liability/ rental risk/disturbance	Hiscox	Multi-risk guarantee cap: - Movable assets: €663,000 - Professional equipment: €594,000 - Financial loss: €200,000 - Occupant's liability: €1,500,000 per claim	movable assets €200	Renewable every year on 8 February
Office space risks - Cambridge (MA)	<i>Commercial general liability</i>	Chubb	Maximum guarantee for damage to leased premises: USD 2,000,000 per insurance period and USD 1,000,000 per claim	-	Renewable every year in July
Directors & Officers liability insurance	Financial consequences resulting from invoking the civil liability of the de jure or de facto directors of the Company (natural person or legal entity) extended to claims brought against it in relation to the IPO Defence costs	AIG	€5,000,000 per insurance period	-	Renewable every year in May
Business travel	As part of business trips: i) Accidents involving personal injury ii) Assistance and repatriation iii) Business travel - consequential physical, material and immaterial damage	Chubb France	Maximum limit: - Personal accidents: €200,000 for death or permanent disability - Support and repatriation: unlimited - Business travel - consequential physical, material and immaterial damage: €7,500,000	-	-
Key person insurance	Death or total loss of autonomy insurance of three executives of the Company	Sogecap	Maximum capital payment of €500,000 per claim	-	Renewable every year
Employee benefits France	Death and disability insurance for employees in France	Legal & General	Guarantee in the event of death, absolute and permanent disability: - payment of a death benefit to the beneficiaries - payment of compensation in case of permanent disability or in case of temporary incapacity for work - rehabilitation allowance	90-day deductible for temporary incapacity for work	Renewable every year on 1 January

Insurance policy	Risks covered	Insurance company or broker	Guarantee amount	Deductibles	Expiry
<i>Worker compensation – employer Liability</i>	Worker compensation and employer liability in the United States	Aon Risk Services Northeast, Inc.	Maximum limit of employer's guarantee: - USD 2,000,000 of overall policy cap - USD 2,000,000 per accident or illness	-	Renewable every year on ¹ July

4.8 Judicial and arbitration proceedings

As of the date of the Registration Document, there are no governmental, judicial or arbitration proceedings, including any proceedings that the Company is aware of, which are pending or that threaten the Group, are likely to have or are having material effects on the Group's financial position or profitability during the last 12 months.

5. COMPANY INFORMATION

5.1 History and evolution of the Company

5.1.1 [Legal and commercial name of the Company](#)

The Company's name is: Voluntis.

5.1.2 [Location and registration number of the Company](#)

The Company is registered in the Paris Trade and Companies Register under the number 439 685 850.

5.1.3 [Date of incorporation and duration](#)

The Company was incorporated on 19 October 2001 for a period of 99 years from the date of its registration in the Trade and Companies Register on 5 November 2001, i.e. until 5 November 2100, unless extended or terminated early.

5.1.4 [Company's head office, legal form, legislation governing its activities](#)

The Company is a French société anonyme with Board of Directors governed by French law, and mainly subject, for its operation, to Articles L. 225-1 et seq. of the French Commercial Code.

The Company's head office is located at 58, Avenue Wagram, 75017 Paris, France.

The contact details of the Company are as follows:

Address of the principal establishment: 22, Quai Gallieni, 92150 Suresnes, France

Telephone: +33 (0) 1 41 38 39 20

Fax: + 33 0) 1 41 38 39 26

E-mail: investors@voluntis.com

Website: www.voluntis.com

Legal Entity Identifier (LEI): 969500NSBH4XTWSGFE04

5.1.5 [Important events in the development of the Group's operations](#)

Important events in the development of the Group's operations:

- | | |
|------|--|
| 2001 | Commencement of Company's operations |
| 2003 | Initial contract with a pharmaceutical firm in France |
| 2004 | Development of the first mobile platform |
| 2005 | Signing of the first contract in the United States of America |
| 2006 | Launch of the Diabeo solution's feasibility study in partnership with CERITD |

- 2007 Launch of the Telediab1 study on the Diabeo solution
- First round of private financing (€2 million)
- 2008 Establishment of a Quality Management System
- Further round of financing (€2.1 million)
- Launch of the Telediab2 study on the VITM Basal solution (previous version of the Insulia solution)
- 2009 Conclusion of a scientific collaboration contract with CERITD
- 2010 Creation of the American subsidiary, Voluntis Inc.
- Initial deployment of products in the United States of America in partnership with the Roche group
- New European regulatory framework for software medical devices
- 2011 Signing of the co-development and licence agreement with Sanofi France and the CERITD
- Publication of clinical results relating to the Diabeo solution (Telediab1)
- 2012 Creation of a medical department within the Group
- Further round of financing (€5.1 million)
- 2013 EC marking obtained for the Diabeo solution, necessary for its marketing
- Creation of the Scientific Committee for Diabetes
- First results of the Telediab2 study
- 2014 Further round of financing (€21 million)
- Relocation of the co-founder and Chief Operating Officer to the United States of America
- Launch of the clinical trial Telesage (Diabeo)
- 2015 Signing of two oncology partnership contracts for the development of medical devices with Roche and AstraZeneca respectively
- Appointment of Eric Elliott as Chairman of the Company's Supervisory Board

- 2016 Signing of major distribution partnerships for the Insulia solution with Sanofi and Verily
- Obtaining of FDA Clearance 510 (k) for the Insulia solution, necessary for its market launch
- Obtaining the EC marking for the Insulia solution
- Favourable opinion of the French health authorities (HAS) of reimbursement status for the Diabeo solution
- End of the recruitment of diabetic patients in the Telesage study (Diabeo)
- Creation of the Scientific Committee for Oncology
- Issue of bonds convertible into Company shares for an amount of €6 million
- 2017 Creation of a commercial force dedicated to insurers ("Payers") in the United States of America
- New regulatory approvals from the FDA for developments of the product Insulia (support for new basal insulins)
- Commercial launch of the Insulia solution in the United States of America
- Publication of decrees necessary for the implementation of remote monitoring experimentation programme in France ("Etapas" programme/ Art. 36 LFSS 2014)
- Relocation of the co-founder and CEO to the United States of America
- Contribution to the creation of the "Digital Therapeutics Alliance" in the United States of America
- ESMO publishes the first results of the feasibility study for the solution developed in collaboration with AstraZeneca for patients treated for ovarian cancer
- Issue of bonds convertible into Company shares for an amount of €3.5 million out of an authorised total of €7.1 million

2018	Launch of the Diabeo solution in France
	Launch of the Insulia solution in France
	Change in governance and change of the Company into a French société anonyme with a Board of Directors
	Signing of a bond with Kreos and subscription by Kreos to the first tranche of a nominal amount of €4 million
	Extension of the partnership with Roche Pharma in oncology and shutdown of the project in the last quarter of the year
	Signing of an agreement with a US insurer, Welldyne Rx, regarding the promotion, price and terms of reimbursement of the Insulia solution by WellDyneRx in the United States of America.
2019	Initial public offering of the Company on Compartment C of the Euronext regulated market in Paris, during which the Group raised €30.1 million.
	Signature of a development agreement with Abbvie for therapeutic software add-ons in the field of immunology.
	Launch of the Theraxium Oncology platform
2019	Subscription by Kreos to two additional tranches for a total amount of €3 million of the bond granted to the Company, bringing the total amount borrowed to €7 million.
	End of the collaboration with Roche Pharma France on the ZEMY breast cancer solution.

5.2 Investments

The Group's investments consist of:

- investments in intangible assets consisting of software development and purchase costs;
- investments in tangible assets primarily consisting of office equipment and materials and computer equipment; and
- investments in financial fixed assets corresponding to deposits, loans and guarantees.

Development costs are recorded as intangible assets if they fulfil certain criteria described in Note 3.6 to the consolidated financial statements prepared pursuant to IFRS for the financial year ended 31 December 2018 found in Section 20.1 of the Registration Document. Research and development costs that do not fulfil the above-mentioned criteria, are recorded under expenses.

5.2.1 [Principal investments made during the last two financial years](#)

Principal investments (in thousands of euros)	2017	2018
Acquisition of intangible assets	997	986
of which: capitalised software development expenses	997	986
other intangible assets	0	0
Acquisition of tangible assets	772	55
Acquisition of financial assets	383	296
TOTAL INVESTMENTS	2,152	1,336

The Group's investments amounted to €1,336 k in 2018 (before disposals), a sharp decrease compared to 2017, when they were €2,152 k.

Intangible investments for the last two years, which have been stable, consist mainly of capitalised R&D expenditures and relate to the functional enrichment of the Theraxium platform, the two basal insulin titration solutions for diabetic patients and the development of the proprietary multi-cancer solution.

The relocation of the Group's main establishment in France in April 2017 made it necessary to invest in fitting out and equipping the new head office, which explains the change in the level of investment in tangible assets in 2018.

Details of the investments are presented in Section 9.2.6 of the Registration Document and in Notes 5.1 and 5.2 to the consolidated financial statements established under IFRS for the year ended 31 December 2018 which can be found in Section 20.1 of the Registration Document.

5.2.2 [Principal current investments](#)

In 2019, the Group intends to pursue its commercial and marketing investments, as well as investment in its products through technological and regulatory developments. New versions of its diabetes and oncology solutions, enhanced with new features to expand the target population of patients who can use its solutions, are under development. This will result in new regulatory clearance requests.

To finance the planned investments, the Group will rely on:

- cash of €19.8 million available at end December 2018;
- the repayment in 2019 of the research tax credit payable for the year ended 31 December 2017 (€1.7 million), which was not collected in 2018 and the research tax credit for 2018, which was valued at €1.8 million; and
- the call for two additional optional tranches for the Kreos loan in April 2019 for €3 million.

5.2.3 [Principal future investments](#)

The Company has not made any significant firm investment commitment at the date of the Registration Document.

6. BUSINESS OVERVIEW

6.1 Overview of activities and developments during the past financial year

Voluntis develops and markets digital therapeutics to help patients with chronic conditions and improve treatment outcomes, more specifically targeting diabetes and oncology.

Our mobile app and web-based digital solutions deliver personalised recommendations directly to patients and their care teams. Uses include dose adjustment, managing side effects, monitoring symptoms and automatic remote analysis of patient results. The recommendations are generated immediately by digitised medical algorithms built on sound scientific intelligence and reinforced by multiple security regulations. Voluntis' state-of-the-art solutions are companion devices that aim to increase treatment efficacy and enable telemedicine, which in turn strengthens collaboration between patients and their care teams.

The past year has seen major advances in the Group's two strategic priority areas. In diabetes, this took the form of effective commercial product launches, and in oncology, the implementation of signed commitments and greater investments in a proprietary solution targeting a range of different cancers. The Company's IPO is a key vector in the continuation of this phase of the Group's development.

The digital therapeutic segment remains very dynamic, both in terms of approval of innovative solutions and in terms of alliances and partnerships.

Commercial and business development

Diabetes

The Group began the commercial launch in France and North America of its Diabeo® and Insulia® solutions in January 2018, together with its partners.

In the United States, the Group is pursuing the creation of its direct sales team with paying bodies, which is reflected in hiring in the sales, marketing, and medical fields.

At the same time, the Group has extended its marketing partnerships in the United States. The Company entered into an agreement with a US payer, WellDyneRx (Pharmacy Benefit Manager managing approximately 850,000 insured persons in the targeted commercial segment). This agreement covers the promotion, price and reimbursement conditions of its Insulia solution by WellDyneRx in the United States of America.

Commercial interactions with payers or players in the US health care system sharply accelerated during the second half of 2018.

Oncology

In Oncology, the Group met the Food & Drug Administration (the "FDA") in January 2018 at a pre-submission meeting, to lay out the regulatory approval process for its multi-cancer monitoring platform.

In oncology once again, the Group developed a multi-indication solution and, as was announced in March 2018, its collaboration with Roche, initially focused on breast cancer, was extended. The assessment of this solution will not be continued as a result of Roche Pharma France's decision to terminate this contract. The clinical evaluation of the Zemy Breast Cancer solution supervised by Roche continued.

The Group actively participates in the sectoral work of the Digital Therapeutics Alliance, of which it is a founding member.

Operational issues

The year 2018 saw the recruitment of new operational resources to support the development of the business in France and the United States.

As a result, the Company's average workforce fell from 91 employees in 2017 to 90 employees in 2018, while the Group's workforce increased from 103 to 107 employees. The total workforce is 112 employees at 31 December 2018, of which 19 (17%) are based in the United States.

Financing

On 29 May 2018, the Company announced that it had successfully completed an IPO on the Euronext Paris regulated market and raised €30.1 million (gross, excluding related costs).

The convertible bonds subscribed in July 2017 and January 2018 and the corresponding accrued interest were converted into share capital at the time of the Company's IPO.

In addition, under a Venture Loan Agreement and a Bond Issue Agreement entered into by the Company and Kreos Capital V (UK) Ltd. on 11 April 2018, the latter paid the nominal amount of €4 million of the bonds issued by the Company on 1 May 2018. Similarly, Kreos Capital V (Expert Fund) L.P. subscribed 70,000 warrants (the "BSA₂₀₁₈-Kreos"), allocated by the Company.

There was a request for additional documentation for the 2017 research tax credit of €1.7 million, and it was not collected until February 2019.

At end December 2018, the Group had €19.8 million in available cash.

Product development

The Group continued investing in these two main therapeutic focuses by:

- enhancing the functionalities and coverage of its diabetes products to hold on to its leadership position and open new geographic and demographic market segments; and
- developing its cancer treatment platform, Theraxium Oncology.

Governance

In April 2018, on the occasion of its IPO, the Company changed its form from a French société anonyme with a supervisory board and board of directors to a French société anonyme with a board of directors.

6.2 The emergence of therapeutic software

Voluntis develops and markets therapeutic software to help patients with chronic conditions and improve treatment outcomes.

Our mobile app and web-based digital solutions deliver personalised recommendations directly to patients and their care teams. Uses include dose adjustment, managing side effects, monitoring symptoms and automatic remote analysis of patient results. The recommendations are generated immediately by digitised medical algorithms built on sound scientific intelligence and reinforced by multiple security regulations. Voluntis' state-of-the-art solutions are companion devices that aim to increase treatment efficacy and enable telemedicine, which in turn strengthens collaboration between patients and their care teams.

While our digital therapeutics are new-generation health solutions, they are classified as healthcare products, which must be approved in clinical trials and submitted for regulatory approval (EC marking in France, FDA approval in the United States). They are available on medical prescription and may be eligible for reimbursement by payers. These solutions are part of the digital transformation of healthcare and meet a need for optimisation of both the efficiency and cost of medicines and treatments.

Voluntis operates in the emerging digital therapeutics sector, a market expected to grow from USD 2 billion in 2017 to USD 8.7 billion by 2025, growing at an average annual rate of 21% between 2017 and 2025.¹ The digital therapeutics segment for diabetes in the United States and Europe was estimated at USD 362 million in 2017 (18% of the global market for digital therapies).² Voluntis is a founding member of the Digital Therapeutics Alliance, an industry representative group formed at the end of 2017.

Voluntis' portfolio of solutions targets diabetes and oncology, the two largest global therapeutic segments, estimated at €58 billion and €192 billion, respectively.³

Voluntis has two therapeutic solutions for diabetes, Insulia® and Diabeo®, both of which are in the marketing phase, following an extensive clinical trial programme conducted in partnership with Sanofi and the French centre for diabetes research and treatment, CERITD⁴. Insulia® and Diabeo® personalise treatment for the disease by recommending insulin doses and providing support for patients through the related telemedicine device. Insulia® is a dedicated therapeutic solution for people with type 2 diabetes (T2D) treated with basal insulin. It is a regulated healthcare product approved for use in North America and Europe. Insulia® is now in the deployment phase through both direct sales - by approaching payer organisations, and indirect sales by non-exclusive distribution partners including Sanofi and Onduo (a Sanofi-Verily joint venture). Diabeo® is intended for type 1 and type 2 diabetes (T1D and T2D) patients treated on a multi-injection or insulin pump regimen. It has regulatory approval in Europe and is the first digital medical device in France to be assessed and accepted by the French National Authority for Health (Haute Autorité de Santé or HAS). Diabeo® is eligible for reimbursement as a healthcare product and is distributed by Sanofi.

Our oncology offer is under development. The aim of the solutions is to improve patient adherence to their treatment regime. The personalised patient follow-up and support are an increasingly important challenge for cancer treatment centres, since treatments frequently cause side effects and negatively impact on quality of life. These symptoms can cause patients to temporarily stop or abandon their treatment or lead to unplanned hospital admissions. Voluntis is developing a proprietary solution targeting a range of different cancers, as well as specific solutions under partnership agreements with the pharmaceutical industry. This is particularly the case for the eCO solution in ovarian cancer in partnership with AstraZeneca. An initial feasibility study of eCO was conducted in a number of hospitals in the United States in close cooperation with the National Cancer Institute (NCI). It demonstrated high treatment compliance rates and patient satisfaction with the solution.

¹ Source: Grand View Research 2017

² Source: Grand View Research 2017

³ Source: Evaluate – Pharma World Preview 2017

⁴ Centre d'Etudes et de Recherches pour l'Intensification du Traitement du Diabète (French Centre for the Study and Research of Diabetes Treatment (CERITD))

Voluntis receives revenue at two stages. At the pre-market stage, Voluntis receives payments at technological, clinical or regulatory milestones, under the terms of agreements with industry partners. At the commercial stage, Voluntis posts revenue from the reimbursement of its solutions by payers. Payments come either directly from payers, or indirectly by way of royalties paid by the industry partners for the use of the therapeutic software.

At the nexus of technological and medical innovation, Voluntis' organisation is built around therapeutic and clinical expertise, combined with software development expertise to ensure compliance with regulations governing medical devices and health data. Moreover, Voluntis is supported by three Scientific Advisory Boards consisting of eminent experts in their field, tasked with making recommendations to the Group. Given the significance of the North American market and the importance of payers in the healthcare system, Voluntis has also opened a Boston based subsidiary and put together a sales team focused on building and developing business with payers in this region.

Theraxium is the technological platform underlying Voluntis digital therapeutics. The core system infrastructure hosts shared functions across all our digital therapies and provides the technical operational platform. Theraxium allows Voluntis to accelerate the development of therapeutic software, in accordance with the stringent quality control procedures for medical devices.

Leveraging Theraxium, Voluntis' goal is to maximise the commercial potential of its diabetes products, round off development and move to marketing its suite of oncology solutions. Based on Theraxium, Voluntis is gradually extending its software portfolio into new therapeutic areas.

Through its solutions portfolio, business model and organisation, Voluntis embodies a new category of company - the digital biotech.

[6.2.1 Digital therapeutics: a new industrial sector](#)

Therapeutic software is part of the emerging digital therapeutics sector.

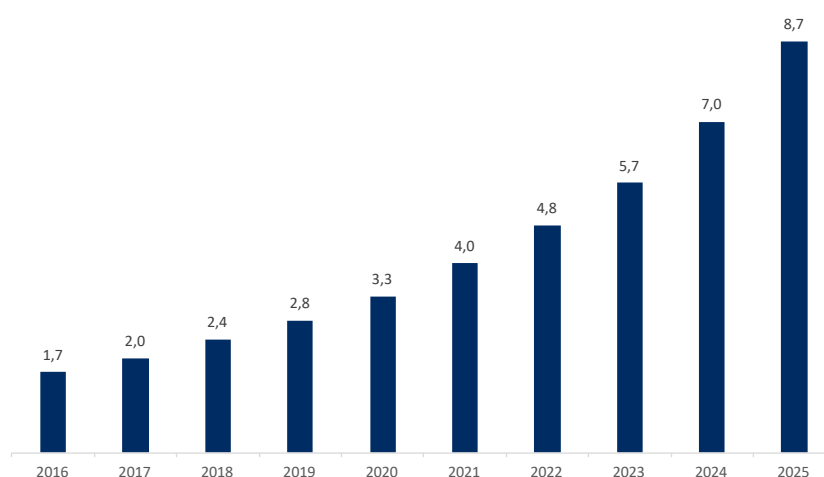
Digital therapeutics are personalised digital solutions for patients to manage their care, provide everyday support and help them to achieve specific disease prevention or management goals. Built on a solid scientific foundation, clinical testing is carried out on these "digiceuticals" to assess their efficacy, just like for any other medicines or physical medical devices.

Digital therapeutics come in two forms: substitutes for existing treatments and treatment companions. The therapeutics developed by Voluntis fall into the second category.

The digital therapeutics market is considered to be one of the fastest-growing digital health segments. A recent industry study estimates the size of this global market, relative to all therapeutic areas, at USD 8.7 billion by 2025 and puts the compound annual growth rate (CAGR) at 21% in the period 2017 to 2025.¹ The digital therapeutics segment for diabetes in the United States and Europe is estimated at USD 362 million in 2017 (18% of the global market for digital therapies).

¹ Source: Grand View Research 2017

Digital therapeutics *market* (in USD billions)



In addition to the benefits offered to patients to self-manage their health, digital therapeutics also play a role in telemedicine, facilitating remote patient monitoring by care teams. These new clinical practices are the focus of interest in many national health systems in a bid to improve the quality of care and enhance treatment efficacy, while also rationalising healthcare costs. Telemedicine is a fast-growing field of e-health. This growth trajectory is underpinned by the emergence of new care structures and the introduction of new pricing schemes to advance the continuity of care for chronic conditions.

In 2018, the digital therapies segment was particularly dynamic in terms of both approvals and the clinical development of innovative solutions and in terms of financing and the signing of alliances and partnerships or consolidation. The progressive structuring of the sector is also reflected in significant media coverage.

6.2.2 [Definition of therapeutic software](#)

Therapeutic software refers to mobile and web applications that deliver recommendations to both patients and healthcare professionals to optimise treatment efficacy. These automated recommendations are generated based on digitised clinical algorithms that process patient data according to a rules engine. The algorithms are built on solid scientific foundations in terms of the content of medical interventions and are strengthened by multiple rules of data security to ensure control of patient risk according to the most stringent standards in the industry.

Fully fledged medical products in their own right, therapeutic software solutions automatically provide patients with their care teams' recommendations, while simultaneously providing healthcare professionals with remote access to patient data as well as analyses to pinpoint recommended actions. This form of collaborative remote monitoring also provides information to determine when to contact patients and if dosage adjustments are needed. The ultimate goal is optimisation of efficacy and tolerance and the prevention of avoidable hospital stays.

Therapeutic software is a means of personalising treatment and enhancing real-life outcomes.

Here are some examples to illustrate some of the key functions of digital therapeutics:

- for the patient, therapeutic software gathers clinical monitoring data and delivers immediate recommendations to adjust dosage, improve management of side effects and monitor symptoms or physical indicators;
- for healthcare professionals, these digital therapeutics provide remote access to patient monitoring data, automatically provide data analysis, identify patients in need of support and recommend possible treatment adjustments.

Data and collaboration between patient and care team are the core of the technology, with information centralised and processed to deliver recommendations: patients and care teams share treatment goals and monitoring indicators, leading ultimately to a deeper understanding of the course of the illness and the actions required. Patients gain valuable reassurance from remote monitoring by their care team. The circulation of data streams is also of benefit for healthcare professionals, as they can share key information and align the teams on shared treatment goals and indicators. Therapeutic software also delivers efficiency gains by managing rights and roles and delegating tasks as needed within the care team. Last but not least, because the software builds in care standards and expert consensus, it can contribute to disseminating best practice and building care protocols to improve quality to the benefit of all.

Therapeutic software generally requires a prescription. The healthcare professional sets the objectives and recommendations to personalise the treatment for the patient when writing the prescription. The prescription stage is also an opportunity to reassure and educate patients.

Therapeutic software is based on medical intelligence and may be treatment- or illness-specific: algorithms inform decisions and relay recommendations based on clinical evaluations and/or expert scientific consensus. Layers of data security rules are built around these algorithms to control independent patient access to the software.

Therapeutic software programmes are classified as medical devices subject to regulation in many countries, especially in Europe and North America. As such, the development process is systematised and governed by audited and certified quality control processes. They must obtain regulatory marketing approval.

As the shift to digital in pharma and healthcare gathers pace, the emerging field of digital therapeutics addresses the challenge of improving treatment and diagnosis, optimising clinical efficacy and improving the real-world cost-benefit ratio of medicines.

[6.2.3 Digital transformation of health: high stakes for public health](#)

New technologies, big data and connected devices are helping to transform medicine with a shift to personalised, predictive, participative and preventive healthcare. At the same time, patients now have broad access to medical information and want a more equal relationship with their care team. Their focus is increasingly on collaboration and involvement in medical decision-making.

Digital transformation is also a priority for public health, with three main objectives: better quality of care for patients, improved health performance indicators and cost control, particularly for health insurance providers and payers.

By encouraging patients to take an active role in managing their condition and intensifying coordination between care teams in a patient focused approach, digital therapeutics play their part in helping to achieve these goals.

6.2.4 [Less-than-optimal treatment efficacy in the real world](#)

Drug treatments reach the market after strict and comprehensive clinical trials and are often an important part of the treatment pathway. Yet, real-world experience - especially when it comes to chronic illnesses - shows that efficacy can fall short. In other words, the results achieved in clinical trials are not fully replicated. Real-world care protocols and patient monitoring may not measure up to the same stringent standards that are the norm for clinical trials. For the patient, this means less frequent contact with their care teams and patchier knowledge of the illness, treatment and treatment goals. The outcome can be poorer compliance with the treatment regimen and less patient involvement.

Treatment compliance is a major issue for all healthcare stakeholders.

- for patients, treatment that is not as effective could mean a poorer quality of life and less hope of a cure;
- for healthcare professionals, non-compliance has a negative impact on the quality of the care they provide, which in turn can lead to loss of revenue in value-based care payment systems;
- insurance providers and payers do not achieve the expected return on the price of the medication and reimburse expenses for care that could have been avoided;
- for the pharmaceutical industry, the variance between real-world efficacy and performance during clinical trials creates downward pressure on prices and on eligibility for reimbursement.

Estimated at €830 billion in 2018, prescription drug sales are expected to increase to €1,204 billion in the period to 2024¹.

6.2.5 [Voluntis and therapeutic software](#)

Voluntis has pioneered therapeutic software since 2001. Voluntis is a founding member of the Digital Therapeutics Alliance (DTA), a global industry representative group formed in December 2017. Other members of the Alliance include Akili Interactive, Pear Therapeutics, Omada Health, Propeller Health and Welldoc. Each member company develops leading edge solutions in different therapeutic areas. Voluntis is the first European digital health company to join the Alliance.

The DTA's mission is to create the conditions for the large scale development of digital therapeutics, and to promote their adoption by healthcare professionals and reimbursement by payers. The Alliance's initial initiatives focused on regulation, sector analyses (particularly to draw up a categorisation and classification system for digital therapeutics) and a campaign to create a new, ad hoc reimbursement framework for digital therapeutics.

¹ Source: EvaluatePharma World Preview 2018 – Outlook to 2024, June 2018

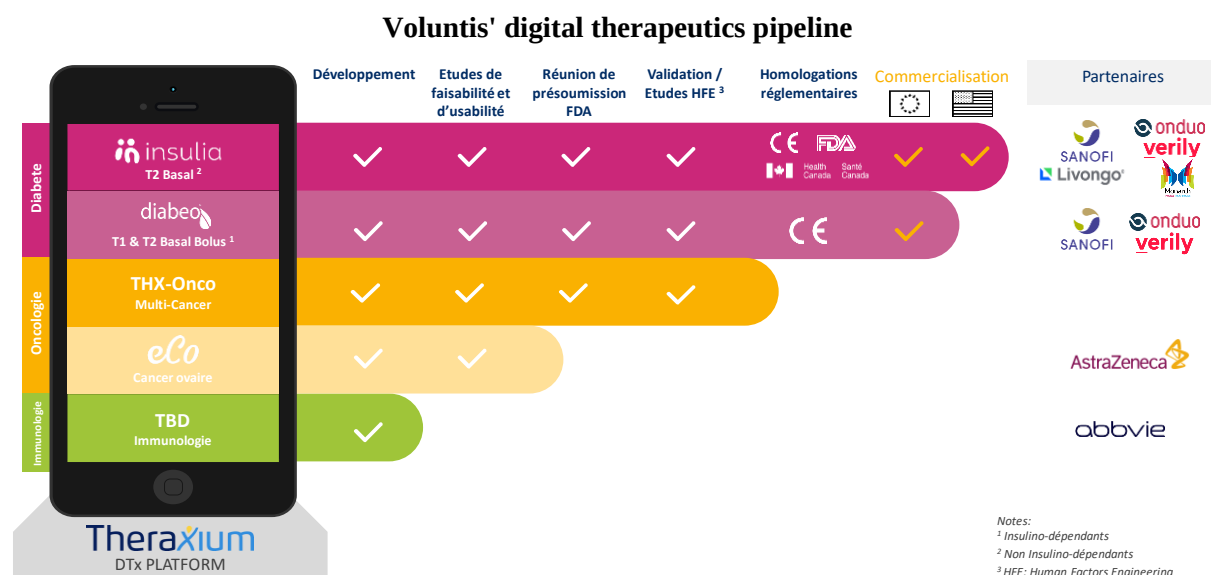
The DTA contributes to the work of the US FDA to support and provide guidance for the development of the FDA's PreCert programme (to certify the companies operating in the digital health sphere and then implement a fast-track market access for their solutions). Designed as a companion to treatments for ¹chronic conditions, Voluntis' therapeutic software aims to personalise treatment, promote coordination between care teams and enhance real-world outcomes. The Theraxium technological platform has been instrumental in developing solutions targeting diabetes, cancer (oncology), haemophilia and blood coagulation conditions. Voluntis' key priority is diabetes and oncology, the largest therapeutic segments in the world, estimated at €58 and €192 billion, respectively².

Voluntis' therapeutic solutions for diabetes have received regulatory approval (FDA clearance in the US and EC marking in Europe) following several clinical trials and are now being commercialised in North America and in Europe.

Voluntis' offer in oncology is under development.

In December 2018, Voluntis expanded its immunology business portfolio through an agreement with AbbVie.

The company is based in Paris and Boston and combines regulatory, R&D, medical, IT and commercial expertise. Based on its Theraxium underlying platform and its certified quality management system, Voluntis contemplate extending its reach to other conditions beyond diabetes and cancer.



¹ Management of chronic diseases is a major public health challenge. In the USA, one of every 2 Americans has at least one chronic disease according to the Centers for Disease Control and Prevention (CDC).

² Source: Evaluate – Pharma World Preview 2017

6.2.6 Business model

6.2.6.1 *Pre-launch revenue*

Voluntis posts revenue streams during the pre-commercialisation stage, under therapeutic software licensing and co-development agreements with industry partners (pharmaceutical firms mainly).

These revenues are a combination of three payment types:

- upfront payments: access rights to the technology (granting a form of exclusivity where relevant);
- milestone payments: payments received at certain key value creation events during product development (such as the granting of regulatory approval);
- co-development payments: development of products or specific functions under the terms of a partnership agreement.

To date, Voluntis has reported over €20 million in pre-launch revenue for its therapeutic software solutions.

Voluntis is one of the first digital health companies to have implemented a digital biotech business model, transposing biopharmaceutical licensing agreements into the digital space. Voluntis entered into agreements of this type with a number of different pharmas since 2011, including Sanofi, Roche, AstraZeneca and AbbVie, for terms that can exceed ten years. These strategic tie-ups give visibility of the Group's future revenue streams. Voluntis is one of the sector companies with the largest number of licencing and co-development agreements currently in force with some of the world's leading life sciences companies.

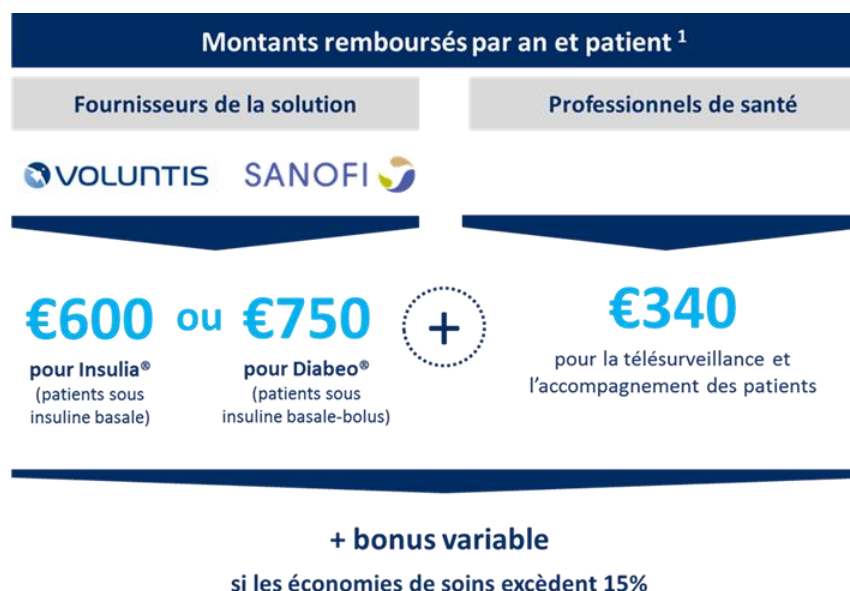
6.2.6.2 *Post-launch revenue*

Revenue in addition to these pre-launch income streams is generated by marketing therapeutic software to healthcare professionals as medical products eligible for reimbursement by payers. The Company's digital therapeutics are marketed either directly by Voluntis or through partnerships, depending on the development context of the solution.

The products are reimbursed either on the basis of the medical device's intrinsic value (standalone reimbursement), or as *a* bundle with another healthcare product or service (bundled *reimbursement*). In the case of bundled reimbursement, the Voluntis solution is paired with another product (such as a medicine or medical device), under the terms of an agreement with a partner marketing an integrated healthcare solution (in which case, there is a single reimbursement payment). The partner (a pharmaceutical firm, for example) handles promotion to health professionals as part of the agreement.

Irrespective of the deal configuration, Voluntis' business model is built around royalties for the therapeutic software (licence fees or *SaaS subscription model*). Fees or subscription amounts may be determined according to actual usage rates (revenue per patient per month/quarter/six-month period/year) and may include a real-world performance-related payment or bonus. Pricing varies by indication and the demonstrated clinical or cost-benefit value.

As an illustration, under the ETAPES (experimental telemedicine programme) standalone reimbursement scheme in France, up to €1,000 per patient *per year* can be reimbursed for Voluntis therapeutic software applied to diabetes. This reimbursement is composed of fixed half-year amounts (€300 to €375, renewable subject to certain conditions) and variable payments, depending on real-world performance, which is evaluated by the French national health payer based on changes in healthcare costs.



¹ Montant annuel maximum remboursé, adossé à des prescriptions valable un semestre et renouvelable, ainsi qu'à des critères d'éligibilité définis en termes d'équilibre glycémique (HbA1c) et de durée de l'insulinothérapie.

The company has negotiated double-digit royalty rates in its commercial agreements signed with pharmaceutical partners. They range from 11 to 50% of the price received by the distributor, based on factors including the level of investment by Voluntis in product development and marketing. The Group estimates that in the future these indirect commercialisation agreements will generate average royalties of approximately 30%.

6.3 Digital therapeutics in diabetes: at commercial stage

Voluntis' diabetes digital therapeutics are designed to support type 1 and type 2 diabetes patients treated with insulin. Two separate solutions have been designed to address two different phases of the insulin therapy pathway. Insulia® is a digital therapeutic for people with type 2 diabetes treated with long-acting basal insulin. Diabeo® is a digital solution for type 1 and type 2 patients treated on a basal-bolus insulin regimen, combining long-acting basal insulin and fast-acting bolus insulin, administered by multiple daily injections (MDI) or pump.

Voluntis is the legal manufacturer of both solutions. Diabeo® is a registered trademark of Sanofi. Insulia® is a registered trademark of Voluntis.

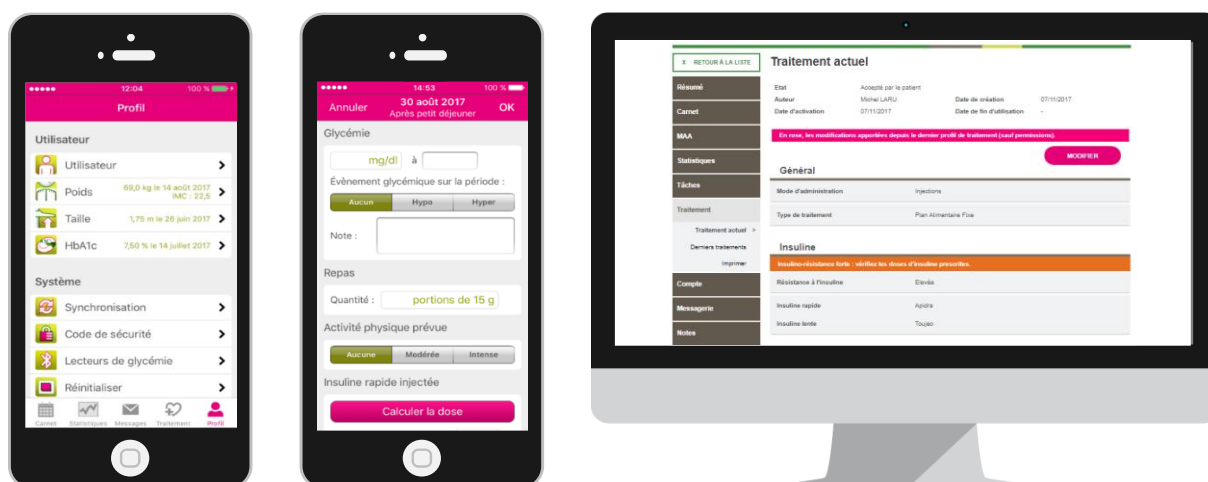
Voluntis' digital therapeutics in diabetes are prescription medical devices.

6.3.1 Diabeo® for diabetes treated on an insulin regimen with multiple injections or pump

Patients with type 1 and type 2 diabetes on a basal-bolus insulin regimen are very actively involved in managing their condition, checking blood glucose (BG) levels and injecting basal and bolus insulin several times a day. Insulin dose adjustment is complex and involves a combination of factors related to glycaemic levels, carbohydrates and physical activity. The dread by patients of hypoglycaemic episodes, sometimes due to excess insulin, is another complicating factor. Lastly, interactions with care teams may not be regular enough to educate patients about their therapy and provide them with sufficient motivation and support. Given these factors, 50% people with type 1 and type 2 diabetes treated on a basal-bolus insulin regimen do not attain the glycaemic target decided on with their care team. However, treatment intensification is no longer possible for these patients already on a basal-bolus multi-injection or pump regimen.

The Company estimates that the number of type 1 and type 2 diabetes patients treated with the basal-bolus insulin regimen totals 3 million in the USA and 2.8 million in the five leading European markets (1 million in Germany, 0.7 million in Italy, 0.4 million in Spain and the UK and 0.35 million in France).

Voluntis' new-generation prescription solution, Diabeo® was developed in response to the need for personalised and collaborative support for adults with type 1 and type 2 diabetes treated on a basal-bolus regimen.



Diabeo® combines:

- a mobile app to harvest patient data and suggest appropriate insulin dosage for the patient's profile;
- with a telemedicine web portal for healthcare professionals.

Diabeo® is a tailored monitoring tool for healthcare professionals. The attending physician enters the patient's personalised treatment profile in the Diabeo® web portal, together with the glycaemic targets and individualised dose adjustment algorithms when prescribing the solution. This personalised information is also a key factor in patient education. The healthcare professional then tracks all the data entered daily by the patient on this web portal: insulin doses, blood glucose, carbohydrate and physical activity readings. The data facilitates remote monitoring, enabling the care team to intervene remotely to adjust the dosage of long- and fast-acting insulin. Automated data analysis flags abnormal conditions and sends an alert to the healthcare professional, simplifying patient supervision. These automatic analysis messages can be calibrated in line with the patient's targets and the practical organisation of the telemedicine service, especially in terms of frequency and the delegation of roles and responsibilities within the care team. In this sense, Diabeo® optimises the medical team's time.

Diabeo® is a personalised support solution with dynamic insulin dosage calculation for type 1 and type 2 diabetes patients. It delivers suggested insulin doses to the patient, based on the parameters configured with the care team and the person's immediate situation. Patients enter their blood glucose, carbohydrate and physical activity levels and the system returns the suggested individualised insulin dose. The information is automatically collated in the Diabeo® patient logbook and sent to the care team to simplify remote support. Glycaemic data can be entered in the Diabeo® log automatically using a compatible reader connected to the device. Patients can also enter the blood glucose readings from a CGM (continuous glucose monitor). Diabeo® provides ongoing support to patients, whatever their meal plan, functional insulin therapy or a fixed meal programme.

Diabeo® is compatible with the majority of therapies available for adult patients with type 1 and type 2 diabetes treated on a basal-bolus regimen.

It is the first digital medical device to be assessed and approved by the French national health authority (HAS). Diabeo® is available under the ETAPES (*Expérimentations de Télémédecine pour l'Amélioration du Parcours En Santé*) pilot telemedicine programme in France. The eligible reimbursement amount is €375 per patient per six-month period, plus a performance bonus calculated according to potential healthcare savings. The performance bonus corresponds to a variable premium which is calculated and paid by the public authorities based on changes in healthcare costs. Therefore, if the reduction in healthcare costs is greater than 15% compared to the previous year, the public authorities agree to repay 50% of the incremental saving to the different players, according to a predefined distribution plan (30% for the technology supplier and 20% for the healthcare professionals).

Diabeo® is marketed by Sanofi.

Diabeo® is a regulated healthcare product that was granted a CE Mark in 2013. Authorised in Europe, Diabeo® is not approved for use in the United States.

6.3.2 [Insulia® for people with type 2 diabetes \(noninsulin-dependent diabetes\)](#)

Insulia® fulfils major unmet medical needs. Patients with type 2 diabetes require insulin when their glycated haemoglobin stays above 7-8%, despite treatment with oral anti-diabetics or GLP-1 analogue. The conventional treatment path is to start insulin treatment with long-acting basal insulin, administered by once-daily subcutaneous injection. But this can be a challenging transition for both the medical team and the patient, and treatment compliance is of paramount importance. Treatment is determined by defining agreed targets and ensuring that the patient can manage their treatment independently. Diabetes patients starting an insulin regimen have to learn to self-inject, adjust the insulin doses, monitor their blood glucose levels and manage episodes of hypoglycaemia (insufficient blood glucose). Naturally, all of these elements are intimately linked: patients check their fasting blood glucose daily with a glucose monitor and adjust their insulin dose according to the reading and their blood glucose targets. If hypoglycaemia (or low blood glucose) occurs - a serious condition that can be aggravated by taking insulin - patients have to know the protocol to follow (taking sugar or glucagon, checking their blood glucose at regular intervals, and avoiding certain activities). The learning curve is steep and calls for ongoing therapeutic support from the care team as well as regular check-ups. In the clinical trial setting, the patients are tightly controlled following specific protocols with high-touch follow-up and support. But in the real-world, the patients do not achieve the same level of independent management of all aspects of their therapy in their daily life. Many patients break off their treatment, neglect to make the necessary adjustments to their insulin dose, become discouraged if their blood glucose levels do not improve or dread having a hypoglycaemic episode. This type of outcome is common and often aggravated by infrequent contact with medical staff and by the fact that hyperglycaemia (abnormally high blood glucose in layman's terms) is often asymptomatic. More than 70% of all insulin treated patients in the USA and the five major European countries do not attain the target blood glucose control level of 7% HbA1c in their normal daily lives, despite the proven clinical efficacy of insulin¹. This suboptimal outcome must also be seen in conjunction with the high treatment drop-off rate, estimated

¹ Source: D. Mauricio et al. – “Glycaemic control and hypoglycaemia burden in patients with type 2 diabetes initiating basal insulin in Europe and the USA” – Diabetes Obesity and Metabolism 2017;19:1155–1164.

at 40% of the patients in the USA¹ after one year and, more generally, in a range between one-third and half of all patients in different regions.

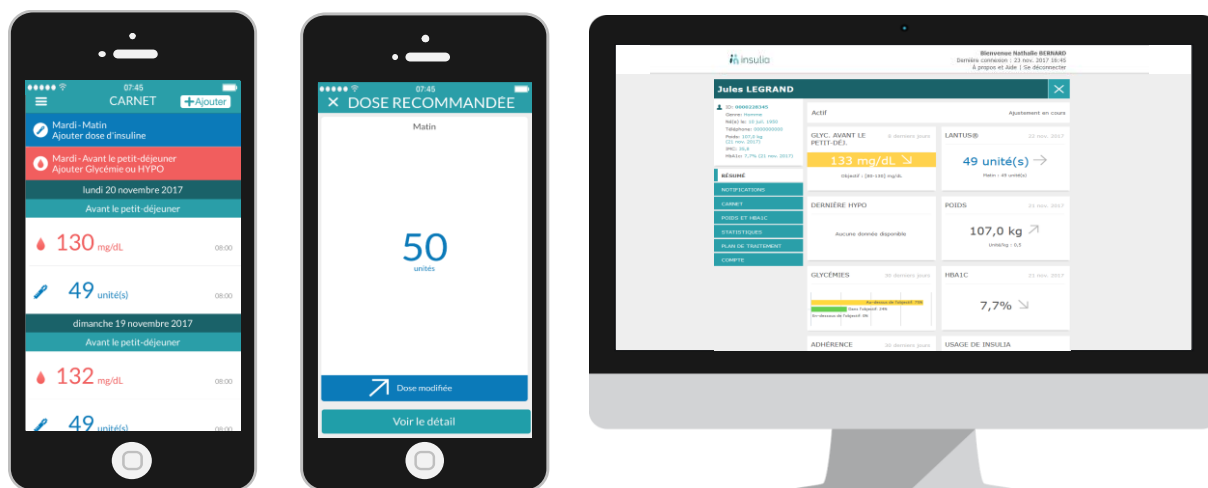
From a healthcare professional standpoint, support for type 2 diabetes patients during this critical phase of treatment can also be difficult. Resources are generally insufficient (time, people and technology) to provide support for patients being treated with basal insulin with the result that treatment tends to be initiated later when the patient's blood glucose imbalance is already well established. In most countries, this treatment stage is managed by general practitioners for the most part (in the United States, France and Germany), although endocrinologists and specialist centres have a more prominent role in countries like Italy.

From a payer point of view, suboptimal efficiency of basal-insulin treatment represents a substantial financial challenge. Blood glucose control is vital in the short-term to prevent the need for unplanned hospitalisation, caused by low blood glucose, and to prevent diabetes-related complications in the medium-term. The UK Prospective Diabetes Study (UKPDS) demonstrated that lowering HbA1c by 1 point reduced peripheral arteriopathies by 43%, micro-vascular complications by 37%, the occurrence of myocardial infarction by 14% and diabetes related mortality by 21%.

The Company estimates that the number of type 2 diabetes patients treated with long-acting basal insulin (outside a basal-bolus regimen) is 6 million in the USA and 2 million for the five leading European markets (0.6 million in Germany, 0.4 million in Spain and in France, 0.3 million in Italy and 0.2 million in the UK).

The new generation prescription solution, Insulia® provides individualised support for adult type 2 diabetes patients treated with basal insulin.

¹ Source: Medicare and Commercial Populations. Wei et al. "Benchmarking Insulin Treatment Persistence Among Patients with Type 2 Diabetes Across Different U.S. Payer Segments" – J Manag Care Spec Pharm, 2017 Mar;23(3):278-290



Insulia® combines:

- a mobile or web application for the patient to harvest data and suggest appropriate insulin dosage for their profile;
- with a telemedicine web portal for healthcare professionals to personalise the prescription and provide patients with remote support.

Insulia® is a tailored monitoring tool for healthcare professionals. The attending physician enters the patient's personalised treatment plan in the Insulia® web portal and configures the algorithms to calculate the insulin dosage according to best practice parameters, such as blood glucose targets, initial insulin dose, patient weight, dose adjustment frequency or injection frequency. The solution includes more than 300 possible treatment plans to tailor the regimen to the patient's individual profile. Personalised settings are critical when it comes to defining agreed goals, motivating patients and educating them about their condition and how to manage it. The healthcare professional then tracks all the data entered daily by the patient on this web portal: basal insulin dose injected, blood glucose levels, hypoglycaemic episodes. Automated analyses and configurable notifications notify the medical team of abnormalities, such as hypoglycaemia, prolonged blood glucose imbalance or failure to follow the dosage recommendations. The data facilitates remote patient monitoring and allows the team to contact the patient or intervene remotely to adjust the dosage of basal insulin if need be.

Insulia® is a personalised support solution with individualised insulin dosage calculation for type 2 diabetes patients treated with basal insulin. It delivers suggested insulin doses to the patient, based on the parameters configured with the care team and the person's immediate situation. Patients enter their blood glucose every day, as well as any symptoms of hypoglycaemia and the system returns the suggested individualised basal insulin dose. The information is automatically collated in the Insulia® patient follow-up log and sent to the care team to enable remote support. Besides the insulin dose recommendations, patients also receive educational coaching messages.

The Group is continually enhancing the functionality of Insulia® and expanding the coverage of basal insulin types managed by Insulia®. In March 2019, the Group announced that it obtained European regulatory approval for a new version of Insulia® that incorporates Neutral Protamine Hagedorn (NPH) intermediate-acting insulin. This version is also being reviewed by the US regulatory authorities. In total, Insulia® is now compatible with almost all basal insulin treatments available to adults with type 2 diabetes.

Insulia® is available under the ETAPES (*Expérimentations de Télémedecine pour l'Amélioration du Parcours En Santé*) pilot telemedicine programme in France. The eligible reimbursement amount is €300 per patient per six-month period, plus a bonus calculated according to potential healthcare savings.

The Group also deployed Insulia®, initially as part of pilots, in Canada and Germany. These pilots were deployed, in collaboration with a pharmaceutical partner, to collect real life data and evaluate both the integration of the solution into the uses and the methods of promoting the solution. The Group plans to deploy pilots in the United Kingdom in the first half of 2019.

Available only on prescription, Insulia® is a regulated healthcare product that was granted the EC marking (in Europe) and FDA clearance (in the US) in November 2016. Insulia® also received Canadian market approval early in 2018.

6.3.3 [Business model based on reimbursement from payers](#)

The economic burden (USD 727 billion globally in 2017) is such that diabetes is unquestionably one of the top concerns for payers as they increasingly focus on improved efficacy, better quality of care and more active patient involvement in managing their condition.

Payers are keen to contemplate the adoption of solutions that enhances clinical efficacy through better blood glucose control, reduced unplanned hospital stays, implementation of protocol-based care pathways and improved organisational productivity of care teams (with information sharing, delegation, and coordination of care).

The economic benefits of Voluntis' digital therapeutics flow from some or all of the impacts below:

- short-term impact on cost savings:
 - fewer hospitalisations (for hypoglycaemic episodes, for example),
 - increased patient empowerment and autonomy, reducing the need for nursing care,
 - delayed treatment intensification to more expensive medicines or devices. For example, optimised treatment of type 2 diabetes with basal insulin alone leads to delaying the need for the patient to progress to an intensified basal-bolus insulin regimen or a combination basal-GLP1 treatment (basal insulin combined with a glucagon-like peptide-1 analogue), which are more costly therapies for the health system,
 - optimised organisational costs, thanks to optimised information sharing in the medical team and delegation of responsibilities to nursing staff remotely monitoring patient progress,
 - Reduced hospital transport needed (due to remote monitoring);
- Medium- to long-term impact, which is the result of reduced care need as complications are avoided. For example, the total care costs reimbursed in France to diabetic patients with terminal chronic renal failure treated with dialysis or kidney transplant amounts to more than €65,000 per year, compared with €5,431 on average per diabetes patient per year¹.

¹ Source: Institut de Veille Sanitaire – Representative national sample of diabetics, Entred 2007-2010

Recent modelling by US health insurance companies shows a gross reduction of USD 4,690 in annual costs if patients were perfectly compliant with their treatment regimens¹.

A simple calculation suffices to calculate the net savings generated by digital therapeutics. We subtract from the gross savings total: the cost of the solutions, the cost of the additional telemedicine activities, and the increased reimbursement amounts associated with optimum use of health products and services by patients (in diabetes: higher use of medicines as per the prescription, more frequent self-monitoring of blood glucose levels, and a larger number of lab tests).

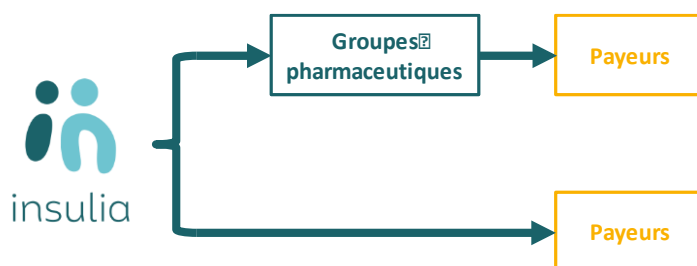
American insurers are increasingly rolling out telemedicine products and services to contain costs and optimise anti-diabetic treatments. Based on an analysis of benchmarks, the payers' willingness-to-pay to reimburse such technological and/or organisational innovations can be estimated between USD 700 and 1,500 on average per patient per year².

The Company estimates it could allow US payers to benefit from a return on investment of up to 5:1 via, on the one hand, the estimated impact in terms of reduction of medical care expenses³ and, on the other hand, the delay in intensifying treatment towards more expensive drug therapies⁴. This estimated medico-economic⁵ impact assumes an Insulia solution list price of USD 900 per patient per year in the USA (for an estimated average price of around €500 per year⁶).

6.3.4 Strategic partnerships and dual distribution policy

Insulia[®] came on the market at the end of 2017 through two complementary channels:

- distribution by leading industry partners (e.g. Sanofi);
- direct approach to payers by Voluntis.



¹ Source: Express Scripts 2016

² Télémédecine 2020 white paper, Syntec Numéric and SNITEM, and company communications

³ A one-point drop in HbA1c generates a 3-year saving of over USD 3,600 according to the study by Fitch, K. et al. Journal of Managed Care Pharmacy, 2013. 19(8): 609-620.

⁴ Taking into account the prices of therapies following basal insulin in the line of treatment: Basal/GLP-1, or Basal-Bolus combos (prices referred to on www.goodrx.com March 2018).

⁵ The medico-economic assessment also incorporates a projected trend, for payers, of the drug item resulting from the increased dosage of insulin in order to reach optimal dosage for the patient. For example, patients treated with insulin glargine in the USA consume less than 30 units per day in real life, compared to 45 to 70 units per day in clinical studies with forced titration, according to the Diabetes Obes Metab 2017 study; 2017(2017):2017–2017. 19(3):375–386. “A real-world study of treatment patterns and outcomes in US managed-care patients with type 2 Diabetes initiating injectable therapies”.

⁶ The average projected price is lower than the list price due to the fact that different parameters are taken into account: fraction of patients, who discontinue the use of the (churn) solution early or who do not achieve their treatment goal (which impacts performance-related payments), and any reductions granted to payers in contractual negotiations (e.g. in exchange for large user volumes).

The Group began marketing its solutions for diabetes in 2017 in the USA and in France in 2018. The Group also deployed Insulia® initially as pilots in Canada and Germany. The Group plans to deploy pilots in the United Kingdom in the first half of 2019.

6.3.4.1 Distribution intermediated by leading partners

In 2017, Voluntis announced the signing of two major distribution partnerships with Sanofi and with Onduo, a joint venture between Sanofi and Verily (formerly Google Life Sciences). These are non-exclusive worldwide distribution agreements for Insulia® and Diabeo®, excluding France, for which the exclusive deal signed in 2011 with Sanofi France and CERITD for Diabeo® remains in force.

Under these agreements, Voluntis gains the benefit of its partners' global reach to distribute its digital therapeutics worldwide, while leveraging their therapeutic and commercial expertise to gain access to healthcare professionals and payers.

For Sanofi and Onduo, the tie-up adds insulin dosage to their offering, combining medicines, diagnostic devices and coaching services for a comprehensive approach to diabetes care.

Under the terms of the agreements, Sanofi and Onduo bill payers for the use of these integrated health solutions and pay royalties to Voluntis, calculated by actual use of the software by patients.

Voluntis has also established commercial and technological partnerships with Livongo and Monarch to combine Insulia® with solutions with additional functionalities and thus broaden the offer to healthcare professionals who assist in the management of type 2 diabetes, initially in the United States.

Patients and medical teams have access to the company's therapeutic software solutions, directly or through strategic partners, as separate medical devices or as integrated modules on population health management platforms, alongside other modules (blood glucose monitoring, nutritional and physical activity coaching, for example).

6.3.4.2 Direct distribution to healthcare professionals and payers

Voluntis considers it is strategically compelling to promote Insulia® directly to healthcare professionals and payers, in parallel with the distribution operated through top-ranking industry partners.

The product is marketed directly in regions in which the company has an established presence, namely in the United States and France, as well as in other markets in which the health authorities are very open to digital therapeutics, including the United Kingdom or Germany.

In the USA, marketing, price setting and the reimbursement of Insulia® are generally decentralised at the level of each insurer or health provider, on an ad hoc basis. Since 2017, Voluntis has had a team capable of seeking and signing contracts with payers and healthcare providers, effectively supporting deployment and ensuring customer satisfaction. The American healthcare system is fragmented; therefore, the company's approach is based on detailed market segmentation and the careful targeting of payers. Thus, integrated delivery networks, commercial plans, private payers in charge of the public programs Medicare and Medicaid (Medicare Advantage, Managed Medicaid) and pharmacy benefit managers are priority segments targeted by the Company.

The table below describes the priority segments targeted by the Company and their potential in terms of number of patients using Voluntis' therapeutic software in diabetes¹.

Target US payer segments	Total number of accounts	Priority targets and potential addressable population of diabetic users
Integrated Delivery Networks (IDNs) E.g. Kaiser Permanente, Geisinger, Intermountain Healthcare	More than 600	40 accounts, corresponding to 25 million lives covered and potential addressable number of patient users estimated at 450,000.
Commercial Health Plans E.g. United Healthcare, Cigna, Aetna, Blue Cross Blue Shield, Harvard Pilgrim	More than 225	64 accounts, corresponding to 178 million lives covered and potential addressable number of patient users estimated at 3.2 million.
Pharmacy Benefit Managers (PBMs) E.g. Express Scripts, CVS, OptumRx, Prime Therapeutics	More than 40	16 accounts corresponding to an extra 62 million lives covered on top of those covered by Commercial Health Plans, and a potential additional number of patient users estimated at 1.1 million.
Medicare Advantage Health Plans E.g. United Healthcare, Cigna, Humana	More than 200	50 accounts, corresponding to 13 million lives covered and potential addressable number of patient users estimated at 520,000.
Employers	This segment is targeted by the Company through distribution partnerships.	

To market its solutions directly to paying agencies and healthcare providers, the Group is pursuing the development of its sales team, which is supported by Medical Sciences Liaisons (MSLs) and customer success managers.

In 2018, the Company entered into an initial agreement with a US pharmacy benefit manager, WelldyneRx, which manages approximately 850,000 policyholders in the target business segment. Commercial interactions with payers or players in the US health care system sharply accelerated during 2018.

¹ For an "average" American payer covering 1 million people, given that there is a 9% prevalence of diabetes and that approx. 20% of the patients are treated with basal insulin, the Company estimates that approx. 18,000 insured persons having type 2 diabetes are treated with basal insulin and could potentially use Insulvia.

More and more American payers cover telemedicine solutions and/or digital therapeutics. Integrated delivery networks are set up to provide both patient care (hospitals, practices and other facilities) and insurance (some of the best-known examples include Kaiser Permanente and Veterans Health Administration). They have frequently led the change when it comes to the large-scale uptake of telemedicine services by their policyholders. The CCHT (Care Coordination/Home Telehealth) programme for army veterans is often referred to as the earliest and most wide-ranging initiative of its kind by the US government. The programme monitors more than 100,000 veterans remotely. More recently, digital therapeutics companies have started marketing their solutions to employers and private payers as a component of public health management programmes. One notable example is Omada Health, a behavioural change programme focused on diabetes prevention. It has been used by in excess of 140,000 employees and is billed according to an outcomes-based pricing model. New partnership models are emerging: digital therapeutics companies are teaming up with Pharmacy Benefit Managers to make a combined approach to employers and private insurers. Examples of such collaborations include the partnership between Propeller Health and Express Scripts in respiratory care and the collaboration between Click Therapeutics and Magellan Health in the area of smoking cessation.

CMS (Centres for Medicare and Medicaid Services) has also created new reimbursement codes designed to encourage the development of remote monitoring practices for chronically ill patients covered by the Medicare health insurance plan. These new codes (CPT 99453, CPT 99454 and CPT 99457) were operational from 1 January 2019. The Company intends to capitalise on the emergence of these codes, which represent an important lever for encouraging healthcare professionals to change their practices by using remote technological solutions. In this context, solutions are marketed first with healthcare providers who bill Medicare themselves using the CPT codes.

In France, Voluntis markets its solutions as part of the ETAPES programme promoted by the French authorities in accordance with the Decree of 25 April 2017 that sets out specifications for experiments relating to the management by remote monitoring of diabetes, on the basis of Article 36 of Law No. 2013-1203 for the financing of social security in 2014. ETAPES set the reimbursement by the French authorities for the provision of the software solution by the provider and the remote monitoring and therapeutic support by the care teams. The amount repaid to the supplier for the software was set at i) €300 per patient per six-month period for type 2 diabetes treated with once-daily injection of basal insulin, and ii) €375 per patient per six-month period for type 1 or 2 diabetes on a multi-injection basal-bolus regimen. On top of these flat payments, the health authorities also instituted a system of sharing incremental savings on healthcare costs with the healthcare professionals and companies responsible for the reduction in costs above a fixed threshold. The benefit of these measures is to align the objectives of all actors involved in the treatment and care of diabetes. The programme is one of the most ambitious to be launched in a European country to promote the development of telemedicine on a national scale. ETAPES is part of the French government's National Health Strategy and gives priority to the development of digital health.

Voluntis recognises the full revenue generated from marketing its products to payers and/or healthcare providers under a direct distribution system.

6.4 Digital therapeutics in oncology: in development

Voluntis oncology solutions aim to improve patient adherence to drug treatments, so as to enable them to draw maximum benefits from their treatment. The therapeutic software offers personalised help to patients in different cancer settings to better manage their symptoms, improve treatment monitoring and provide better care overall. Prescribed by care teams as an extension of treatment, they help patients better manage their symptoms and side effects and facilitate remote monitoring by medical staff.

6.4.1 [Cancer and managing symptoms](#)

A large number of patients with cancer are treated with chemotherapy. In the USA, for example, approx. 22% of the cancer patients are treated with chemotherapy for a year¹. 650,000 American patients are treated in outpatient oncology clinics every year². Furthermore, a number of new therapies are oral (25 to 30%) and ³are taken by the patient on his/her own at home. Adherence to these new therapies is suboptimal: it is estimated that 37% of the patients do not follow the recommended treatment properly⁴. Finally, up to 60% of the patients express treatment-related discomfort⁵.

Treatments for cancer very often cause side effects for patients. They can have a marked impact on patients' quality of life and ability to stay functional. Symptoms can range in severity and often result in patients stopping their treatment temporarily or definitely or lead to unscheduled hospitalisation. Managing symptoms is therefore a cornerstone of clinical practice in oncology centres. Yet, healthcare professionals generally do not have the tools they need to monitor symptoms and discussions during consultations rarely give the full picture.

The symptoms linked to these treatments have a significant economic impact. Therefore, the cost of hospitalisation linked to an episode of severe diarrhoea for an American patient is estimated to be USD 8,443. Likewise, an uncontrolled episode of nausea and vomiting can cost up to USD 1,575 more per month than a controlled episode. Likewise, a severe episode of mucositis (inflammation of the oral mucosa) costs twice as much as it does to handle a more moderate episode (USD 4,100 versus USD 1,936⁶).

American payers have launched programmes aimed at providing increased support to patients throughout their course of treatment. This approach, which includes help to manage symptoms, has proven its economic effectiveness in terms of remote interventions by medical personnel. For example, a United Healthcare pilot study indicated an annual saving of USD 13,092 for patients monitored via such a specialty pharmacy programme vs. a standard retail pharmacy follow-up, mainly by preventing avoidable hospitalisations or visits to accident & emergency (and by taking into account additional expenses related to the drug item, because of better adherence to the treatment⁷).

The results of a major study on patient-reported outcomes for symptom monitoring during routine cancer treatment were presented during the 2017 ASCO (American Society of Clinical Oncology) international meeting. The trial showed that proactive monitoring by the care team of the symptoms reported on a web platform by patients improved quality of life from 18% (in the standard care arm of the trial) to 34%, reduced unplanned hospitalisations by 7% (34% vs. 41%), increased treatment duration to 8.2 months from 6.3 months, and increased overall survival by 5 months⁸. 75% of patients were still alive after 12 months, compared to 69% on the web platform.

Therapeutic software is an integral component of this collaborative approach, as information on symptoms is continuously shared between patients and their care teams. Smart medical algorithms can be added to automatically send recommendations to patients to help them self-manage some symptoms, and to the medical team, to identify and track the progress of these symptoms.

6.4.2 A solution targeting a range of different cancers

Voluntis' global oncology strategy includes the development of a solution for multiple cancers. It will target a large population of patients receiving both older-generation drug therapy (chemotherapy) and newer-generation targeted therapies and immunotherapy. Voluntis' solution aims to enhance control of the most frequently found reversible symptoms that can be managed according to current practices. It covers a dozen or so symptoms (such as diarrhoea, nausea and vomiting and pain) and is intended for patients with high-incidence cancers, such as lung cancer, colorectal cancer and melanoma. The solution has a modular design to fit individual needs. For example, management of a particular symptom can be disabled or treatment algorithms can be added. It will help to accelerate more targeted solutions specific to a particular type of cancer or a particular treatment regimen.

In January 2018, Voluntis held a meeting with the US Food and Drug Administration (FDA) staff under the Medical Devices Pre-Submission Program to clarify the regulatory pathway for obtaining United States market approval for this multiple cancer solution. The Company's target timeline is to obtain FDA approval for version 1 in the second half of 2019 and a first EC marking for the solution in the first half of 2020. The Company's track record in diabetes regulatory approvals constitutes an important advantage when it comes to implementing a comparable process in oncology.

If regulatory approval is obtained in the US, Voluntis intends to directly distribute this solution at cancer treatment centres in the United States from the first half of 2020. It will be distributed to both local and research centres. Voluntis will also apply for the EC marking for a similar distribution strategy in Europe.

In addition, Voluntis plans to launch a multi-centre evaluation in the United States in 2019 to assess the clinical benefits and cost effectiveness of its multi-cancer solution. The criteria evaluated relate to improvement in the quality of life, reduction of severe toxicity, reduction in emergency visits and the number of unscheduled hospitalisations, as well as the decrease in health costs. Based on the results of this evaluation, the Group will seek reimbursement of its solution by payers.

The Group expects the initial marketing of the solution developed in partnership with the pharmaceutical industry, as well as the signing of the first direct marketing agreements with US health insurers, to take place in the first half of 2021.

6.4.3 [Development of solutions in partnership with the pharmaceutical industry](#)

Regarding breast cancer, in October 2015 Voluntis signed a partnership with Roche Pharma France in order to develop and distribute ZEMY, a solution based on the Theraxium Oncologie platform. In

March 2019, the Group announced Roche Pharma France's decision not to continue its partnership with Voluntis on this project beyond the clinical feasibility study carried out by Roche Pharma France, scheduled for late April 2019.

For ovarian cancer, in close cooperation with AstraZeneca and the US National Cancer Institute (NCI), the Group has developed a companion solution for women undergoing treatment for recurrent platinum-sensitive high-grade ovarian cancer with cediranib (a VEGFR1-3 inhibitor) in combination with olaparib (PARP inhibitor). The service is delivered through a smartphone application paired with a web portal that enables clinicians to help patients manage treatment side effects of hypertension and diarrhoea sometimes associated with combination therapy of cediranib and olaparib.

An initial feasibility study was conducted in the United States in a number of leading cancer centres, including the Dana Farber Cancer Institute, Moffitt Cancer Center, Ohio State University Medical Center, and the National Cancer Institute. Results showed a high level of patient compliance and satisfaction with the solution – over 98% of expected blood pressure measurements were collected by patients. These results were published in the JCO® Clinical Cancer Informatics in June 2018¹.

In October 2018, this app was awarded the Prix Galien – MedStartUp Award for 'Best Patient Engagement Technologies'.

6.5 **The regulatory environment for therapeutic software**

6.5.1 [Regulation of therapeutic software as medical devices](#)

Digital therapeutics embed clinical algorithms and deliver real-time recommendations to patients to optimise their treatment. They are classed as medical devices under the regulations. Accordingly, their design and development are managed following certified processes and regulatory approval is required for each solution.

To ensure full compliance with all regulations on medical devices, Voluntis formed a Quality Assurance and Regulatory Affairs team in both France and the United States. It also introduced a quality management system to meet the requirements of the main international regulatory bodies in Europe and the US (FDA 21 CFR part 820 and EU Directive 93/42/EEC). Its quality systems and processes have been certified ISO13485 for medical device since 2010. Voluntis is audited on a regular basis to ensure compliance.

Moreover, Voluntis also applies ISO 14971 relative to risk management for medical devices. The Company's production process also follow international standard IEC 62304 defining the lifecycle requirements for medical device software, as well as IEC 62366, which specifies the process for the assessment of usability of medical devices.

All our validation engineers are certified by the International Software Testing Qualifications Board (ISTQB).

¹ Liu JF, et al. Technology Applications: Use of Digital Health Technology to Enable Drug Development. JCO Clinical Cancer Informatics. 2018(2):1-12.

Voluntis' solutions obtain regulatory approval from the relevant competent local bodies, based on an ad hoc submission. The submission generally includes for each solution: the intended use, technical and clinical characteristics, development process applied, report of each validation and testing stage, risk assessment, labelling elements, usability assessment ("HFE") and clinical assessment. The regulatory approval application file contains all the information required by the competent authorities to rule on the safety and efficacy of the therapeutic software for its claimed use.

The competent regulatory authorities (the FDA in the US and in Europe, a notified body - the LNE-GMED in the Group's case) will grant regulatory approvals once the safety and efficacy of the device has been evaluated with regard to its claimed use.

In the case of Voluntis solutions, the evaluation of these elements in the USA is based primarily on the demonstration of substantial equivalence with a device that has already been approved (510(k) procedure). To support this demonstration, an application is submitted to the regulatory authorities. This submission includes the intended use of the device, its technical and clinical features, the development and validation processes implemented, the risk analysis, HFE studies, labelling items and clinical evaluation. The clinical evaluation includes the review of the scientific literature, such as, for example, all of the existing clinical studies, recommendations from medical societies and expert opinions. The clinical evaluation may also include clinical studies performed by the manufacturer specifically for this device. The manufacturer does not have to perform these studies, unless the data from the scientific literature is insufficient to demonstrate the safety and efficacy of the device. The regulatory approval application contains all the information required by the competent authorities to rule on the safety and efficacy of the therapeutic software for its intended use. This section is optional, unless the device evaluated is not substantially equivalent to an already approved device.

[6.5.2 French regulation of telemedicine](#)

Article L. 6316-1 of the French Public Health Code (*Code de la santé publique*, CSP) provides the basic definition of telemedicine. It is defined as "a form of remote medical practice using information and communication technology. It connects one or more healthcare professionals or healthcare professionals with a patient, which must include a medical professional and, where relevant, other professionals providing care to the patient. Telemedicine activities include making a diagnosis, providing preventive or post-therapeutic monitoring for at-risk patients, seeking a specialist opinion, preparing a treatment decision, prescribing products, prescribing or carrying out services or actions, or monitoring the patient's condition". Decree 2010-1229 of 19 October 2010 defines the legal and regulatory framework for telemedicine by defining the medical procedures and setting out the conditions for their performance and payment.

Telemedicine acts are defined as:

- remote consultation (a medical professional performs a consultation with a patient remotely);
- remote expertise (a medical professional seeks the opinion of one or more medical professionals remotely);
- remote patient monitoring (a medical professional can remotely interpret data to provide medical follow-up to a patient);
- remote medical assistance (a medical professional can provide remote assistance to another health professional during a medical procedure);
- medical response (as part of emergency medical service).

The decree provides the legal framework governing the conditions for providing telemedicine services. The main requirements are:

- to obtain patients' free and informed consent;
- a certain amount of information must be entered in the patient's medical record, such as the report of the actual performance of the medical act or procedure, prescriptions, and all arrangements for subsequent follow-up; and
- payment of the medical acts in accordance with agreed conditions and the CCAM (*Classification Commune des Actes Médicaux*, French medical classification for clinical procedures).

To be legally valid, all telemedicine activities and their organisation must be covered by:

- either a national programme specified by order of the ministers with responsibility for health, the elderly, the disabled and health insurance;
- or a registration in one of the multi-year contracts or in one of the contract aimed at improving care quality and coordination, such as those mentioned respectively in Articles L. 6114-1, L. 1435-3 and L. 1435-4 of the French Public Health Code, and in Articles L. 313-11 and L. 313-12 of the Family and Social Action Code (*Code de l'action sociale et des familles*);
- or by an individual contract signed by the Director General of the regional health agency and the health professional, or where relevant, anybody involved in this activity.

6.5.3 [Data privacy regulations](#) [Voluntis is committed to protecting data privacy.](#)

All the Company's work is conducted in strict compliance with the principles and requirements of applicable regulations: the French data protection act, known as the "Information Technology, Data Files and Civil Liberty law", European Directive 95/46/EC, and the General Data Protection Regulation (GDPR), as well as the Health Insurance Portability and Accountability Act (HIPAA) in America.

Voluntis implements a Privacy by Design model that embeds data protection at every stage of the therapeutic software processes. Voluntis' software medical devices are designed to keep the collection of personal health data to the minimum required for the clinical algorithm processing and to ensure the security of the data. The Company always informs and seeks the consent of the users of its digital therapeutics to make sure that individuals' rights are never infringed. Voluntis also provides users with access to their data, as well as the ability to rectify or to oppose the processing of their information. Retention of personal health data is strictly a function of the period of time required for patient care. Data are subsequently archived in accordance with the law. Users have the right to be forgotten and have their data deleted. In addition, Voluntis systematically assesses the impact of its devices on users' private life.

Access to data is restricted to authorised individuals, under the conditions specified in the authorisations received by Voluntis. Any secondary use of the data shall be made in accordance with the requirements of the supervisory authorities, in particular with regard to information to individuals.

All health data collected by Voluntis are hosted by subcontractors in compliance with applicable legislation: Accredited health data hosting (HADS) in France and HIPAA in the United States. In partnership with these hosting providers, the Company implements security requirements at every stage of the product's use (strong authentication for healthcare professionals and patients, encryption of stored and transmitted data, data integrity checks at each synchronisation). Voluntis has a cybersecurity team and carries out regular hacking checks.

6.5.4 [Legal and economic framework for e-health and telemedicine solutions](#)

Voluntis' Chief Executive Officer is a key contributor to the development of the e-health sector. As such, he is actively engaged in sector projects to promote digital health.

In France, Pierre Leurent is the General Coordinator for Alliance eHealth France, a partnership between four professional organisations (LEEM, LESISS, SNITEM and *Syntec Numérique*) representing almost all e-health solution suppliers.

Voluntis is a driving force in the sector and actively contributes to the development of e-health projects, through its engagement in market research (the Telemedicine 2020 studies conducted by Syntec Numérique and SNITEM from 2011 to 2014), France's industrial policy plans, Nouvelle France Industrielle (2013-2014 Digital Healthcare Plan, 2015-2016 Medicine of the Future Plan), ministerial strategic committees (strategic healthcare industries council (CSIS) and the Industry Strategy Committee (CSF)), position papers, presidential platform (helping to draw up Syntec Numérique's campaign programme), membership of working groups formed by or with government authorities, promoting dialogue on the policies implemented by government (such as the ETAPES Programme).

Across the Atlantic in the United States, Pierre Leurent has occupied leadership sectorial positions to contribute to advancing the digital therapeutics space since 2017:

- member of the Board of Directors, co-founder of Digital Therapeutics Alliance;
- co-director of the Digital Therapeutics Task Force of the Personal Connected Health Alliance (member of HIMSS).

6.6 **Voluntis: organisation and growth trajectory**

Voluntis has had a unique growth trajectory – the one of a software company having become a life sciences company.

Voluntis was founded in 2001 by three graduate engineers from the Ecole Centrale de Paris (now CentraleSupélec) focused initially on technology and software expertise.

It shifted gears in 2002 to market its proprietary software platform Medpassport (precursor of the Theraxium platform), a B2B model to provide patient monitoring and support. Voluntis pioneered SaaS solutions in the healthcare sector and grew its revenue through multi-year subscription contracts to the software platform. Voluntis's first business model is known in the industry as Patient Relationship Management (PRM). The platform's clients included top industry players, such as AstraZeneca, Pfizer, Sanofi, Orkyn (Air Liquide group), Respironics (since taken over by Philips), Axa Assistance, Mondial Assistance and Bien-Etre Assistance. The business was initially centred in Europe for patient relationship management in c. 20 therapeutic areas: diabetes, cardiovascular, respiratory, oncology, nutrition and rare diseases, amongst others.

Voluntis's installed base grew steadily to 500,000 patients supported in 10 countries through these various programmes.

Voluntis raised €4 million in private equity in the period 2006 to 2011 to fund its growth and reached breakeven in 2011.

But Voluntis's transformative vision led it to go beyond these B2B programmes to develop innovative therapeutic offerings built on medical intelligence. In 2005, in a partnership with CERITD, Voluntis released the first version of the Diabeo® software, one of the global firsts in digital therapeutic development. Well before the launch of the iPhone in 2007, it was one of the first mobile health apps embedding patient decision support algorithms for the management of chronic illnesses.

Three crucial developments between 2010 and 2012 led to significant changes in Voluntis's business model:

- regulatory changes in the United States and in Europe: software like Diabeo® and Insulia®, used as diagnostic and/or treatment tools, became regulated as medical devices (the change took effect in France in March 2010 when the European directive was transposed into French law);
- the results of the TELEDIAB1 multi-centre randomised controlled trial (published in the leading journal Diabetes Care in 2011): the results demonstrated the positive impact of the Diabeo solution on glycemic control in type 1 diabetic patients. TELEDIAB1 was one of the first global examples of a clinical trial on software and ushered in the potential to market the device as a medical product eligible for reimbursement by healthcare payers; and
- the 2011 licensing and co-development agreement with Sanofi, in partnership with CERITD, for Diabeo®. This long-term agreement was the Company's first agreement according to the terms of a biopharmaceutical licensing deal, rather than a software licence. It was one of the world's first examples of a partnership between a digital therapeutics (DTx) company and a pharma leader.

Following a strategic review of the growth and potential of its two core business areas, PRM and DTx, senior management decided in 2012 to shift the focus of the Company exclusively to the development and commercialisation of digital therapeutics and to gradually phase out its legacy PRM business.

This decision led to a radical transformation of the Company's organisation as it shifted from a software company into a healthcare company. To strengthen its talent, Voluntis recruited expert profiles from the pharma industry in 2011-2012 to join its management team.

With the change in business model to a digital biotech came a corresponding increase in capital requirements, compared with the financing previously required by the PRM business. To meet these needs, the Company raised an additional €5 million in 2012, followed by €34 million in a number of different tranches as of 2014. Voluntis successfully completed the largest private equity round of funding for a digital health company in Europe in 2014, in a placement with European and North American investors.

Two new departments were formed through the transformation to a health company:

- quality and Regulatory Affairs department: Voluntis' processes are overseen according to a quality management and control system that meets the requirements of the main regulatory bodies in Europe and United States, with the appropriate teams: Quality Assurance and Regulatory Affairs, engineers specialising in risk management, software verification, approval and human factors engineering. These expert teams now make up c. 40% of the Voluntis workforce. The Company has a system of internal standards and procedures, as well as dedicated management and steering tools. The Quality Assurance and Regulatory Affairs teams are the point of contact for notified and audit bodies. They coordinate with external auditors and are responsible for organising internal audits according to the annual audit plan. These teams also fulfil the crucial responsibility of protecting user data. The specialist teams and the certified processes are Voluntis' guarantee that the development and deployment of its solutions meet the highest standards of excellence;

- medical Affairs Department: the Medical Affairs Department was formed in 2012 to expand the Company's therapeutic expertise. It is staffed by physicians and nurses who bring extensive clinical and industry experience to the Company. Medical Affairs is structured by therapeutic area and is responsible for the scientific design of the software, clinical trial programmes, medical device vigilance and relationships with health authorities. The department plays a critical role in software development, both upstream (by identifying unmet medical needs, summarising clinical rules for coding by the development teams, organising medical risk analysis or defining indications) and downstream (monitoring the efficacy and security of the software, dialogue with authorities and/or expanding the scope to other indications). Expert Scientific Advisory Boards support the Medical Affairs department in its work in diabetes and oncology. They provide operational insight on the integration of the software in the care delivery pathway and in clinical practice, and also issue recommendations on development priorities. The Medical Affairs Department places the patient at the heart of Voluntis decision-making process.

Two new teams were formed to focus on marketing digital therapeutics following regulatory approval on both sides of the Atlantic in 2016:

- a new sales and marketing team tasked with interacting directly with health insurance and healthcare providers, starting in the United States. This organisational evolution reflects the Company's strategic decision to shift to a dual business model that combines direct and indirect commercialisation to healthcare payers and providers. The team is led by a manager with substantial experience in the North American health payer sector. It is also responsible for modelling the cost effectiveness of Voluntis' solutions;
- a team specialising in analysing real-world evidence. This team is composed of experts with responsibility for analysing and exploiting real-world results based on deidentified aggregate data.

In parallel with the creation of these new departments, the Group's technological operations have been continually strengthened in terms of expertise, particularly regarding IT architecture, cyber security and artificial intelligence.

The Company recognised very early on the need to scale up and make a determined international push, giving priority to the US market, to leverage its pioneering position and establish Voluntis as a global digital therapeutics leader. A subsidiary was established on the East coast in 2011 and two of the Company's three co-founders relocated to the US, in 2014 and 2017, respectively. Voluntis beefed up the American component of its governance in both its senior management team and its Board of Directors. 2015 saw a senior executive from the United States payer and PBM industry join the Company as non-executive Chairman to further drive this gradual transformation of Voluntis and establish a dual structure with a footprint in Europe and North America. In 2018, this transformation was consolidated with the recruitment of two new independent directors from the US, boasting significant experience in the American healthcare market.

6.7 Technological platform

Theraxium is the technology platform underlying all the Company's digital therapeutics. This infrastructure platform includes features common to all solutions and is designed to accelerate development of therapeutic software, in accordance with the stringent quality control procedures for medical devices. Theraxium manages data flows and underpins the technical operation of the Group's therapeutic software, in strict compliance with privacy, security and safety rules.

Cloud-based, Theraxium is a modular platform that forms the cornerstone of Voluntis' digital therapeutics. It serves to:

- collect patient data, according to a set of strict cybersecurity and data protection rules (authentication, synchronisation, encryption and hosting);
- retrieve data from third-party devices, using wireless interoperability and integration management protocols;
- provide access to data and data sharing through configurable roles and delegated authorities in care teams;
- analyse data, using an analytics suite that incorporates automated notification or dashboards to support medical decisions;
- secure clinical algorithms by providing a framework for the prescription process and automating recalls of software medical devices.

The Theraxium platform also speeds up the development of new digital therapeutics building on its algorithm engine and preconfigured functional modules. Its underlying algorithms, built around DSL (domain specific language) methodologies, facilitate the creation of algorithms with the ability to rapidly develop prototypes with medical experts. The web-based and mobile execution engine enables simulation and the more effective and secure deployment facilitates regulatory approval and optimises maintenance.

Theraxium also incorporates layers that are purpose developed for specific therapeutic areas, such as oncology. These layers are built around algorithms defined for the pathology and the components needed to display, store and share the data related to the algorithms.

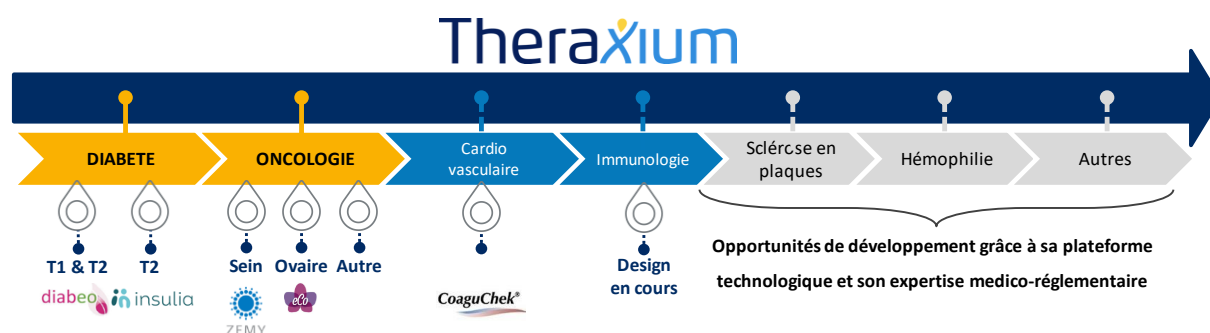
In addition, Theraxium includes preconfigured functional modules designed to be used by most therapeutic software suites. Management of user accounts, user interfaces and data flows on our platform demonstrate Theraxium's agility and ability to be used - and reused - across multiple solutions.

Theraxium is a proprietary platform developed end-to-end by Voluntis, without any third party input, involving more than one million lines of code. Besides its accumulated expertise and know-how, Theraxium is protected by a procedural patent (Procedure and system to create a virtual platform intended to facilitate the sharing of disease management data – FR2843215, filed in France). New patent applications have been filed to cover some of the Theraxium modules (Secure prescription of a medical software device - WO2016128636 and Procedure and system for remotely monitoring a medical software device - WO2014125235)

The Theraxium platform is operated and managed by Voluntis from data centres located in Europe and the United States. Our data centres are secure, duly accredited for the secure hosting of personal health data, highly available and compliant with current regulations applicable to Voluntis in the regions in which it operates (General Data Protection Regulation in Europe and HIPAA in the United States).

Theraxium has proven its reliability through its implementation in 50+ programmes covering more than 20 therapeutic fields. To date, six top 10 pharmaceutical companies have deployed Theraxium (or its predecessor Medpassport) to support patient-centred initiatives. It has provided support and monitoring for over 610,000 patients in 10 countries

In this context, Voluntis can also extend its platform Theraxium beyond its current therapeutic areas and develop new software for other chronic diseases. In December 2018, the Group therefore launched immunology developments, as part of an agreement with AbbVie, one of the global leaders in the sector.

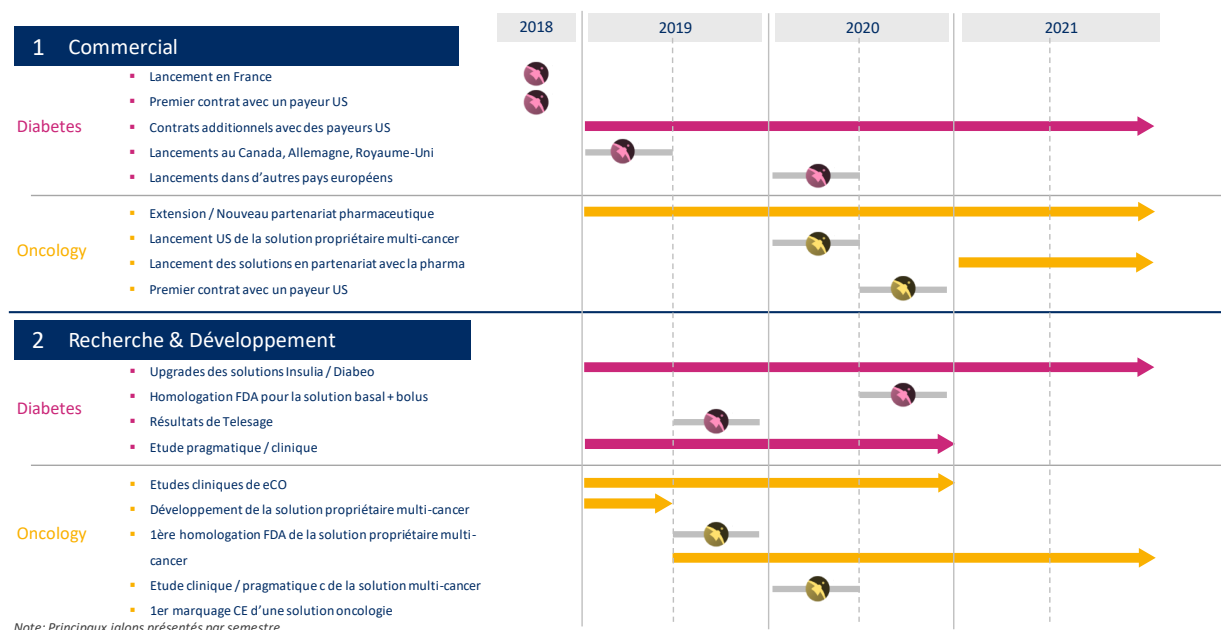


6.8 Priorities in addition to diabetes and oncology

Voluntis' strategic plan prioritises its aims in two stages:

- short term: maximise the commercial potential of diabetes solutions and finalise the development of a suite of solutions in oncology;
- medium term: ramp up the oncology suite to commercial phase and extend the model to other therapeutic areas.

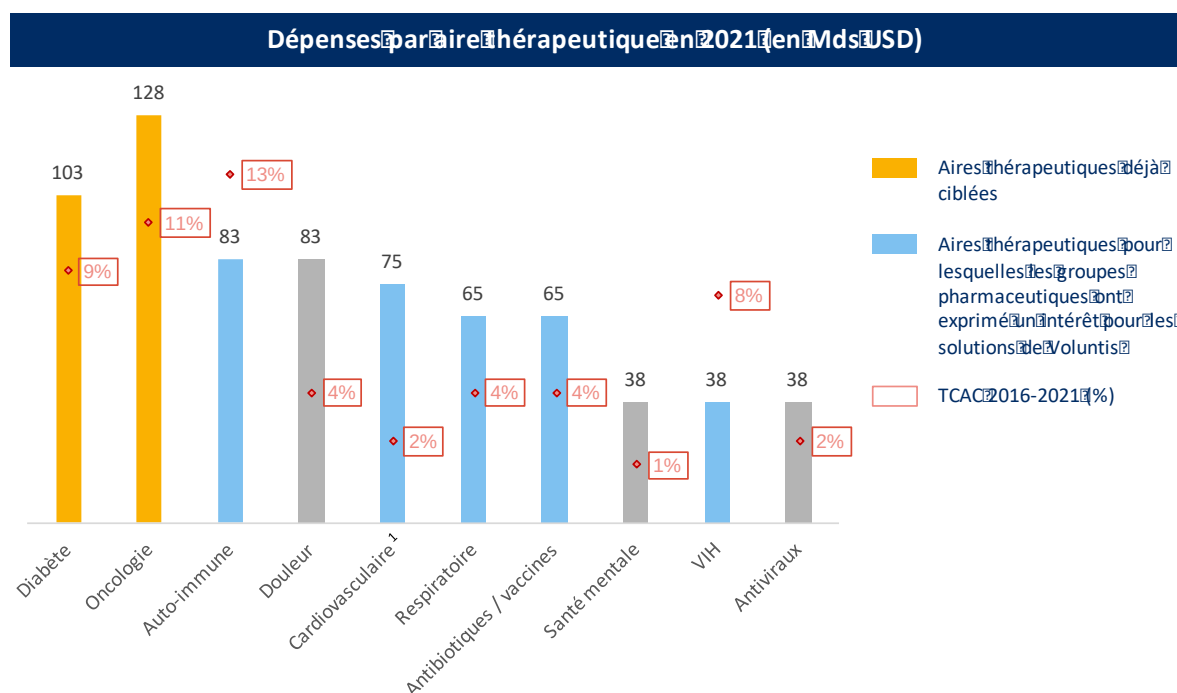
The achievement of these strategic priorities is supported by a R&D and commercial development plan. The main milestones of this plan are summarised below:



Expanding beyond an initial core focus on diabetes and oncology, therapeutic software has the potential to add value to treatments in many other areas.

Voluntis' strategic priorities by therapeutic area are defined according to an analytical matrix that incorporates the following parameters:

- extent of patient engagement in their illness and treatment, based especially on medication self-management or changes in quality of life for the patient and their loved ones;
- degree of healthcare coordination, based on the level of protocolisation and standardisation of care, and the number of healthcare professionals involved in treatment pathway;
- payer concern level, based on prevalence, total cost of the condition, cost of medicines, complications and treatment compliance problems;
- market share in value and volume of treatments and the portfolio issues for pharmas.



¹ Ciblée par Voluntis via CoaguChek - pas une priorité actuelle
 Source: IMS Therapy Prognosis (2016)

There are a number of key factors that determine the success of digital therapeutics in any given therapeutic area:

- focus the services provided by the solution on unmet patient and healthcare professional needs;
- develop the software according to clearly defined processes, combining agility and speed with reliability and security;
- obtain regulatory market approval, which is dependent on having a certified quality assurance system and preparing an ad hoc approval application filing complete with the required data;
- know how to demonstrate the medical and economic benefit of the software by amassing clinical trial or real-world data.

Voluntis has the required expertise and capabilities to ensure these key success factors are in place and to draw on the experience it has gained in diabetes and oncology to replicate models and develop therapeutic software in other therapeutic areas:

- medical expertise to identify unmet medical needs, ensure a deep and detailed understanding of clinical rules to be digitised, and to demonstrate clinical value;
- software development processes combining agility and quality assurance;
- the Theraxium platform designed to share a number of mobile and web functions;
- regulatory expertise to frame therapeutic software development and obtain regulatory market approvals;
- commercial roll-out experience.

Therapeutic software can bring value for the treatment and the management of many conditions. Voluntis can leverage its expertise and capacity to develop many solutions targeting other medical specialties. There are a number of ways of approaching this new opportunity, including proprietary development and co-development partnerships with biopharmaceutical or medical device firms.

Voluntis is currently focusing its investments on establishing and securing a global leadership position in diabetes and oncology. Looking beyond this, the Group may decide to respond to queries from third parties, on a case-by-case basis, to develop therapeutic software as a companion to specific treatments.

One such collaboration is the CoaguChek Link solution developed by Voluntis for Roche Diagnostics in anti-coagulation treatments. This solution collects, shares and analyses the INR data measured by patients treated with Anti-vitamin K and using the CoaguChek device. The platform was launched in the United States in 2010, only six months after signing the contract, through the use of the Voluntis technology platform, for care teams to monitor large numbers of patients on anticoagulants and aid decision-making and dose adjustment. It has helped Roche Diagnostics consolidate its global leading position in a rapidly growing PT/INR self-monitoring market. To date, Roche has brought more than one million CoaguChek devices to market around the world.

Another example is the partnership entered into with AbbVie in December 2018 in the field of immunology. This partnership aims to develop and evaluate a companion therapeutic digital solution in the United States.

6.9 The competitive landscape and key success factors

The digital health market is vast and growing at a rapid pace. The large and diverse range of operators in the market can be broken down into the following main categories:

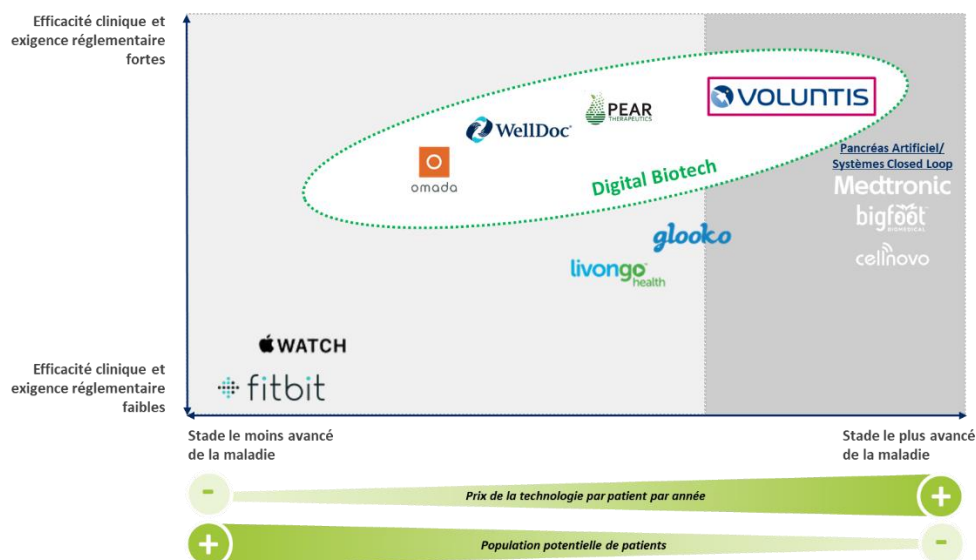
- specialist digital therapeutics/digital biotech firms (notably Omada Health, Welldoc and Pear Therapeutics), which are the closest in profile to Voluntis. Voluntis belongs to this sub-group. Some of these companies – like Voluntis – are members of the Digital Therapeutics Alliance. The solutions developed by Voluntis target relatively late disease stages and are already at an advanced phase in the stringent regulatory approval process. Some products are already on the market after their efficacy was demonstrated in clinical settings. The majority are intended as solutions eligible for reimbursement by payers. Voluntis is one of the most advanced digital biotech companies, with the first solutions to have been cleared by regulators (Insulia® and Diabeo®), and to have been passed by the French health authority (HAS) for reimbursement (Diabeo®). These products carry a relatively high price tag. Their target is smaller than the population aimed at by wellness companies (see below) but generally larger than that of pharmas, biotechs/medtechs.

Other major digital health players of note in the diabetes monitoring space are Livongo Health and Glooko. The table below tracks the positioning and maturity of certain flagship companies in digital therapies:

	Digital Therapeutics								Autres acteurs Digital Health	
Membre de la DTx Alliance	VOLUNTIS	PEAR	AKILI	Propeller	WellDoc	Click Therapeutics	omada		livongo	glooko
Aires thérapeutiques ciblées	• Diabète (T1&T2) • Oncologie	• Neurologie (dépendance opiacés, schizophrénie...)	• TDAH	• Asthme & BPCO	• Diabète	• Dépression sévère • Sevrage tabagique	• Diabète (T2) • Hypertension • Dépression		• Diabète (T1&T2) • Hypertension • Dépression	• Diabète (T1&T2)
Plateforme multi-aires thérapeutiques / focus	✓	✓	✗	✗	✗	✓	✓		✓	✗
Homologations réglementaires	FDA CE Health Canada	FDA	✗	FDA CE	FDA	✗	✗		FDA	FDA
Produits commercialisés	✓	✓	✗	✓	✓	✓	✓		✓	✓
Partenariats avec des industriels des sciences de la vie	SANOFI, AstraZeneca, anduo, obdevie, Roche	NOVARTIS	SHIONOGI	NOVARTIS	Johnson & Johnson	Boehringer Ingelheim	✗		Lilly	Medtronic, Novo Nordisk, Ascensia
Remboursement payeurs	• En développement aux USA • Sécurisé en FR	• En développement aux US		• En développement aux US	• En développement aux USA	• En développement aux USA	• En expansion aux USA		• En expansion aux USA	• En développement aux USA
Dernière opération de financement	€30m (2018)	\$64m (Jan 2019)	\$68m (Août 2018)	Acquisition par Resmed (Dec 2018)	\$30m (Mars 2016)	\$17m (Juillet 2018)	\$50m (Juin 2017)		\$105m (Avril 2018)	\$35m (Juin 2017)
Footprint mondial	USA, Canada, Europe	USA	USA, Japon	USA, Europe	USA, Canada, Inde	USA	USA		USA	USA, Europe

- medtech companies active in diabetes and developing closed loop / artificial pancreas systems (e.g. Medtronic, Bigfoot and Cellnovo). The medical devices in their pipeline target later disease stages and must undergo a stringent regulatory approval process. The majority are intended as solutions eligible for reimbursement by payers. Their products carry a higher price tag and their target population is smaller than the segment of patients aimed at by Voluntis;
- companies developing connected objects in the wellness segment (including Fitbit, Apple Watch, Nokia Digital Health -Withings)

Their main target is people keen to live a healthier lifestyle who have no (or few) symptoms of any particular condition. Their products are connected objects (fitness tracker for Fitbit, watch for Apple Watch, weighing scales for Withings) to track health data (weight, heart rate, etc.), but they are generally not regulated as medical products. Their products do not go through a strict regulatory approval process and are not reimbursed by payer organisations. Connected objects are priced lower than the healthcare products mentioned above and are marketed to a very large target population. They have a preventive role.



The digital therapeutics and therapeutic software market is still relatively sparsely populated. For example, there are more than 318,000 health and wellness apps available¹. Compare this with the much smaller number - around 160² – of solutions approved as medical devices in the United States and/or in Europe, and the even smaller number of solutions whose efficacy has been demonstrated in multi-centre randomised controlled trials. Voluntis is positioned in the high value-added SaMD (Software as a Medical Device) segment. Barriers to entry are high and the Company has few competitors (compared with e-health solutions aimed at the wellness market).

Some medical devices companies are indirectly involved in digital therapeutics: healthcare companies that produce medicines or medical hardware (such as blood glucose monitors, insulin injection pens or pumps in diabetes) are part of the market through the trend to build medical intelligence and connectivity into their devices.

Alongside these medtechs, companies similar to Voluntis in size have a pipeline of software solutions to increase real-world treatment effectiveness. Generally speaking, they specialise in a specific therapeutic area.

Diabetes has attracted a large number of solutions, indicative of the challenge of the disease, with varying approaches reflecting the multi-factor complexity of diabetes. Speciality areas include:

- patient coaching (Livongo, Welldoc);
- harmonised data readings from blood glucose monitors (Glooko);
- insulin dosage solutions (AmalgamRx, Hygieia, Glooko, Roche and Sanofi).

Other companies are positioned in the emerging artificial pancreas segment. This type of integrated model incorporates a continuous blood glucose monitor, insulin pump and software to adjust insulin doses in real time. The priority for this automated insulin adjustment system is patients whose condition is not controlled by alternative therapies. The main names in this segment are Medtronic, Bigfoot Biomedical, DreaMed, Diabeloop and Cellnovo. Voluntis' solutions are complementary products rather than directly competing solutions, either because they aim for other diabetic segments (Insulia for type 2 diabetics, Diabeo for type 1 diabetics on multiple daily injections primarily) or because they are indicated at an earlier stage in the care pathway. Diabeo® is considered an "open-loop system" as opposed to a "closed-loop" insulin delivery system, inasmuch as it is not a device to directly manage insulin injection. An artificial pancreas system - usually more complex and expensive - can come into play in cases of persistent blood sugar imbalance in users of a system like Diabeo®.

Medical information systems in oncology have historically been developed for healthcare professionals to support treatment decision-making as part of a wide range of therapeutic protocols. The leading offers in this segment range from electronic medical records (McKesson, Flatiron) and decision-making tools (IBM Watson Oncology). Patient-focused software, which also provides medical staff with decision-making tools, are a much more recent development. There are relatively few players in this emerging segment. No system comparable to Voluntis' therapeutic software has been approved yet as a medical device in the United States.

¹ Source: IQVIA, November 2017

² Source: Grand View Research 2017

This is a dynamic market environment and Voluntis has a strong hand:

- a top-notch international team with complementary skills and profiles (technology, medical, regulatory, sales and marketing and market access);
- accumulated expertise in the digitisation of medical algorithms in the course of 15 years of software development;
- clinical data, amassed during a number of randomised clinical trials, and real-world data are compelling factors when it comes to convincing healthcare professionals and payers;
- in-depth knowledge of quality assurance and regulatory processes demonstrated during FDA and CE marking approval applications and numerous audits, which is key to market access;
- robust, agile and speedy development process through its Theraxium platform, which ensures fluid data flows and shared developments, with patent-protected technologies;
- partnerships with global pharma leaders with unrivalled clinical development and commercial distribution capacity (Sanofi, Roche and AstraZeneca in particular);
- market access know-how proven by eligibility for reimbursement by payers for our therapeutic software;
- presence straddling both sides of the Atlantic with established capability for large-scale deployment in Europe and North America;
- operational maturity to manage the data of hundreds of thousands of patients in different therapeutic areas and countries.

6.10 Clinical trials and Scientific Advisory Committees

6.10.1 [Clinical studies in diabetes](#)

Insulia® and Diabeo® were conceived as part of an extensive clinical programme including several randomised multi-centre clinical trials conducted in partnership with CERITD, large pharmas (Sanofi and Novo Nordisk) and telecom groups (Orange) in the past 12 years.

The clinical plan started with two conclusive feasibility studies in the period 2005 to 2006:

- PDAphone1 feasibility study; and
- PDAphone2 feasibility study

6.10.1.1 PDAPHONE1 overview (initial version of Diabeo®):

PDAPhone1 is a three-month feasibility study with a cohort of ten type 1 diabetic patients who received five days' training in functional insulin therapy on starting the study. The primary endpoint of the study was to assess the benefit of the therapeutic software to control patients' blood glucose. The software was made available to patients as a smartphone app with three main functions: electronic logbook, insulin dose decision-making aid and remote telephone monitoring of patients. Six telephone consultations were scheduled for each patient in the three months of the study [Charpentier, CERITD].

The study demonstrated that the functional insulin therapy method delivered improved post-prandial blood glucose control (PPG), which was maintained around 1.40 g/l 2h after starting the meal, regardless of the blood glucose level beforehand and the amount of carbohydrates ingested. Improved blood glucose control trajectory observed at the end of the three-month study, with average HbA1c falling from 8.7% to 7.3% at the end of the study. All patients were very satisfied overall with the functional insulin therapy method and considered the system easy to use.

6.10.1.2 PDAPHONE2 overview (initial version of Diabeo®):

PDAPhone2 is the second clinical trial conducted on the initial version of DIABEO® [France, 2009]. The primary endpoint of the study was to confirm the personalised prandial functional insulin therapy algorithms proposed by Howorka [Howorka, 1990].

This was a four-month open study, with no control group, on a cohort of 35 type 1 diabetic patients who already practised functional insulin therapy (FIT). They received initial one-day training on how to manage the smartphone in a hospital.

The system was configured ahead of time for each patient according to their blood glucose targets and their functional insulin therapy parameters.

The study demonstrated that the personalised functional insulin therapy method delivered improved post-prandial blood glucose control (PPG), regardless of the blood glucose level beforehand and the number of portions of carbohydrates. Blood glucose control improved significantly during the study. HbA1c fell from $7.8 \pm 0.6\%$ to $7.3 \pm 0.9\%$ ($p=0.003$) and a trend towards reduced occurrence of hypoglycaemic events was observed. It is important to note that HbA1c improved, even though these patients were already managing FIT and their average FIT parameters were not changed during the study.

The results point to the system's efficacy. In addition, patients used the system effectively and the rate of data input before meals (around 90%) was excellent at the start of the study and maintained throughout the evaluation period. The majority of patients also accepted, nine times out of ten, the insulin dose proposed by the system. The satisfaction questionnaire showed that the bulk of the study patients wanted to keep the system, even at their own expense, rather than revert to the old paper logbook.

6.10.1.3 Telediab1 study (Diabeo®) – (2006-2010)

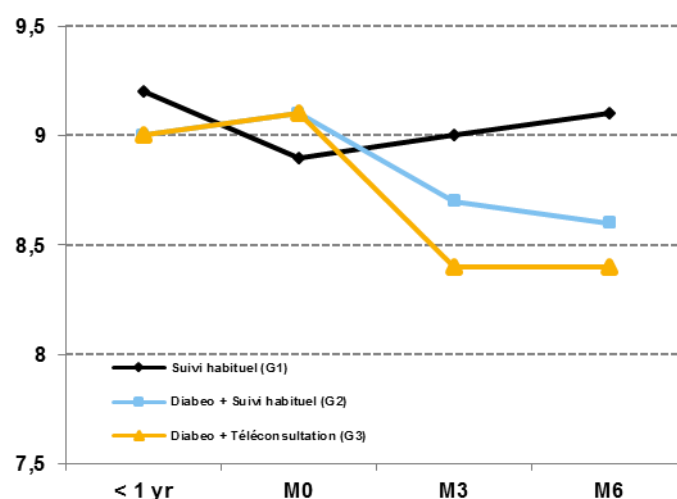
The multi-centre randomised Telediab1 (4) trial demonstrated the efficacy of Diabeo® in uncontrolled type 1 diabetic patients [Charpentier, 2011]. The trial was conducted in 17 hospitals in France on 180 chronically poorly controlled type 1 diabetic patients (HbA1c $\geq 8\%$). The patients were randomised into three groups and tracked for six months.

- Group 1 (G1): control group with standard monitoring in quarterly face-to-face consultations;
- Group 2 (G2): Diabeo® alone with quarterly face-to-face consultations;

- Group 3 (G3): Diabeo® combined with short telephone consultations every two weeks.

Patients were assigned homogeneously on enrolment, with an average HbA1c of $9.07 \pm 1.07\%$, average age of 33.8 ± 12.9 years.

The graph below illustrates the results of the trial at six months for the primary objective, comparison of HbA1c between the three groups:



Patients in the group with Diabeo® alone (G2) improved their HbA1c by 0.7% ($p < 0.01$) at six months (primary criterion), compared with the control group (G1). Patients in the group with Diabeo® plus teleconsultations (G3) improved their HbA1c by 0.9% ($p < 0.001$). The drop-off rate was very small across all groups.

The improved HbA1c was not associated with an increase in hypoglycaemic incidents, particularly severe hypoglycaemic incidents. Incidence was neither significantly different between G1 and G3 (5.5% vs. 1.8%, $P = 0.569$), nor linked to increased frequency of blood glucose self-monitoring.

Although the patients in group 3 (G3) did not check their blood glucose levels any more frequently than the participants in the other two trial groups, they nonetheless achieved a significant improvement in HbA1c, which suggests that they made better use of the self-monitoring information than those in the other two groups.

The total medical consultation time throughout the study duration was the same for all groups (1.2 hours). But the hospital consultation time was far longer (0.5 day) for patients in G1 and G2 than in G3.

The economic indicators from the study were encouraging for G3 patients, who saved time and money on sick leave and transport for hospital visits.

The vast majority of patients were keen to keep their electronic logbook once the trial had ended: 66% for G2 (DIABEO® + conventional monitoring); 75% for G3 (DIABEO® + phone monitoring).

6.10.1.4 Telediab2 trial (previous version of Insulia®) (2008-2013)

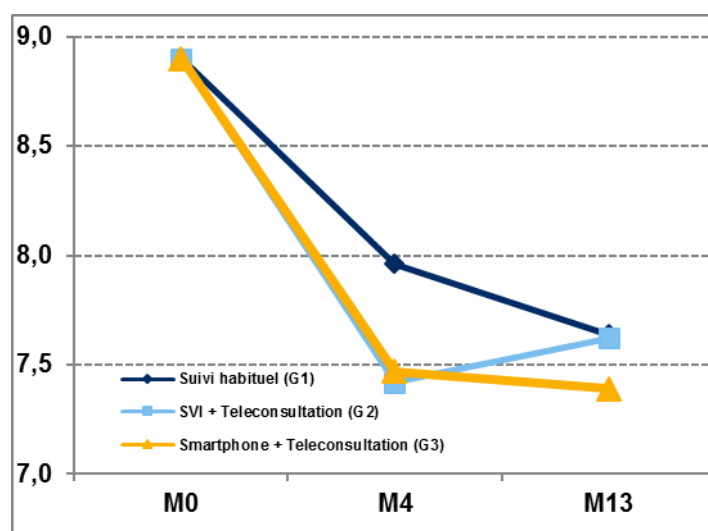
The Telediab2 multi-centre randomised trial demonstrated the efficacy of the VITM basal solution (a previous version of Insulia®) on the management of type 2 diabetes initiating treatment with basal insulin [Daoudi, 2013]. The trial showed a significant improvement in HbA1c at four months, with no concomitant increase in hypoglycaemic risk in the trial arm using VITM Basal.

Conducted in 14 hospitals in France, the trial enrolled 190 poorly controlled type 2 diabetic patients, despite well managed non-insulin treatment (HbA1c $\geq 8\%$). Subjects were randomly assigned to three groups and tracked for four months (M4), subsequently extended to nine months (M13):

- Group 1 (G1): control group with standard monitoring in quarterly face-to-face consultations;
- Group 2 (G2): assigned an interactive voice server (IVS) giving them dose recommendations, plus tele-consultations until M4 (replaced after month four by face-to-face consultations every three months until M13);
- Group 3 (G3): group given VITM Basal smartphone app up to M13, plus tele-consultation every two weeks to M4, and monthly thereafter until M13.

The primary endpoint was the comparison of HbA1c at M4 between G2 and G3 versus G1.

The graph below summarises the results of the trial:



Favourable impact of the device at M4 was observed. Patients from the IVR or smartphone groups saw a decrease in HbA1c significantly higher than those in the control group: [G2 (-1.44%); G3 (-1.48%) and G1 (-0.92%; $p=0.0017$ for G2 vs. G1 and G3 vs. G1 comparisons].

This improvement went along with normalised fasting blood glucose: the number of patients who achieved the target ($< 110\text{mg/dL}$) doubled relative to the control group [(G2) 82.5%; (G3) 82.7% and (G1) 41.8%]. Moreover, efficacy was associated with a good safety profile, with no severe hypoglycaemic event reported. The incidence of mild hypoglycaemic incidents was similar across all three trial groups.

Patients were monitored for an additional nine months (up to M13). At the end of month 13, HbA1c in G2 subjects rose to the same level as G1 patients, whereas it was maintained in the smartphone group (G3). Twice as many G3 patients achieved HbA1c $< 7\%$ compared with the other two trial groups [(G3)39.6 vs. (G1+G2)18.7%; $p=0.007$]. Insulin doses at M13 were: (44 ± 29 ; 44 ± 30 ; 60 ± 45 U ns) and there was no difference in the number of hypoglycaemic incidents, weight and medical time used.

6.10.1.5 Telesage study (Diabeo)® – Under way as at the date of this Registration Document

Telesage is one of the largest clinical and medico-economic trials of a telemedicine product in diabetes [Telesage, NCT02287532]. It is currently under way in France in 95 hospitals and doctors' practices. The aim of the study is to confirm the clinical efficacy of Diabeo® over a longer observation time frame and in a more diversified population than in the Telediab1 trial. Telesage will also evaluate the medical-economic and organisational impact of Diabeo®.

667 type 1 and type 2 diabetic subjects treated on a basal-bolus insulin regimen with poorly controlled diabetes (HbA1c $\geq$ 8%) have been enrolled in the trial and randomly assigned into three treatment groups:

- Group 1: standard monitoring with face-to-face consultations;
- Group 2: Diabeo® software combined with a standard monitoring with face-to-face consultations;
- Group 3: Diabeo® software combined with a tele-monitoring performed by a telemedicine nurse under delegation.

The primary endpoint is the change in HbA1c at 12 months from the baseline initial value. The secondary endpoints will examine the utility scores derived from the EQ-5D health questionnaire at 12 and 24 months, with a particular focus on hypoglycaemia, the use of the Diabeo® system by the trial subjects, patient and physician satisfaction with Diabeo®, and resources used.

In order to conduct the TELESAGE study, a Scientific Committee whose primary tasks focus on the design, conduct and monitoring of the trial has been set up: it is chaired by Dr Guillaume Charpentier (CERITD) and twelve diabetes experts from contributing regional coordination centres: S. Franc (Corbeil), Y. Reznik (Caen), P.Y. Benhamou (Grenoble), H. Hanaire (Toulouse), E. Renard (Montpellier), B. Guercy (Corbeil), A. Penformis (Besançon), D. Raccah (Marseilles), L. Chaillous (Nantes), N. Jeandidier (Strasbourg), P. Fontaine (Lille), B. Catargi (Bordeaux); one medical-economic expert: Bruno Detournay; and one telemedicine expert: Pierre Simon.

The Group anticipates that the first results of the TELESAGE study will be published in the second half of 2018 (first results at the end of one year monitoring patients).

6.10.2 Clinical trials in oncology

6.10.2.1 Summary of the eCO study

In ovarian cancer, the eCO application is being tested as a medical device in independent clinical trials sponsored by the NCI under a Cooperative Research and Development Agreement between the NCI and AstraZeneca. An initial feasibility study was conducted in the United States in a number of prestigious cancer centres, including the Dana Farber Cancer Institute, Moffitt Cancer Center, Ohio State University Medical Center, and the National Cancer Institute. It demonstrated elevated compliance and patient satisfaction with the solution [Liu, 2017].

This open, uncontrolled, multi-centre feasibility study evaluated the eCO app which includes algorithms that manage two significant side effects associated with the treatment combining olaparib and cediranib, the frequency of which was determined to be high in previous studies. A total of 18 patients suffering from ovarian cancer included in a phase II study for this combination (NCTY02345265) took part in the study; the final patient was included on 30 June 2017. They were equipped with the eCO device which, on top of the therapeutic software, included the use of a Bluetooth blood pressure monitor.

After using the device for four weeks, usability and user satisfaction were evaluated and analysed using the Wilcoxon Rank Sum Analysis method. The results showed that the patients felt connected to their care team, felt involved in their own treatment and were satisfied with the ease of use and the majority of the functions of the eCO ($\alpha < .01$). eCO made it possible to collect 98.1% of all blood pressure data. 13 of the 16 patients reported episodes of diarrhoea lasting on average two days, the majority of which were Grade 1 (29 Grade 1 and 4 Grade II out of 33 inputs).

6.10.2.2 Summary of the ZEMY study

The ZEMY app will be evaluated in breast cancer in a clinical trial launched in France early in 2018. It is being conducted in six oncology centers - UNICANCER and independent hospitals - and 56 patients to assess its clinical, organisational and economic benefits. The breast cancer patients will be included at early and metastatic stage of the disease, and receive chemotherapy, targeted therapy or combination therapy.

This is an open, uncontrolled and multi-centre study. Intervention based on the ZEMY device will consist of using the app to manage the 10 most frequent symptoms found in these patients. The first patient was included in the second quarter of 2018 and the study is scheduled to end in April 2019.

The primary endpoints of this study is to assess the number and rate of symptoms reported by patients. The secondary objectives concern the relevance and number of automated messages and recommendations, usability and user satisfaction (patients and healthcare professionals), the safety of the device (software defects, adverse effects related to the device) and the impact on quality of life (EQ5D5L, QLQC30 and BR23 scales). The following will be evaluated: impact on adherence to treatment (e.g. delays, interruptions) and on the use of medical resources (visits to emergency departments, unplanned hospitalisations, time spent by the different categories of medical personnel).

6.10.3 Scientific Advisory Boards

Three Scientific Advisory Boards support Voluntis' work. Reflecting the Company's commitment to advancing treatment in its core areas of focus, the Boards' main role is to provide expert support and critical insight for our product development, to assess and guarantee the scientific validity of the embedded algorithms, and to guide clinical development, communication and market access plans.

Voluntis' objective in forming these advisory boards was to create a panel of international distinguished multi-disciplinary experts around its key centres of interest. Hence, three committees were formed: the international diabetology Scientific Advisory Board, and two oncology Advisory Boards (one American and one European).

The main committee selection criteria give priority to eminence, relevant medical and healthcare specialisations, dual engineering and medical expertise, as well as fundamental and clinical research work.

Comité Scientifique dans le diabète



 Guillaume Charpentier, MD Président Centre d'étude et de recherche pour l'intensification du traitement du diabète (CERITD)	 Ananda Basu, MD, PhD Professeur de Médecine Endocrinologie, Diabète, Métabolisme et Nutrition Université de Virginie Charlottesville	 Rita Basu, MD, PhD Professeur de Médecine Endocrinologie, Diabète, Métabolisme et Nutrition Université de Virginie Charlottesville	 Bernard Harris, MD, MBA Président Directeur Général Vesalius Ventures, Inc.
 Athena Philis-Tsimikas, MD Vice-Présidente Scripps Whittier Diabetes	 Eugene Wright, Jr., MD Conseiller Principal, affaires médicales Cape Fear Valley Health System	 David Klonoff, MD Rédacteur en Chef Diabetes Technology Journal Directeur Médical Diabetes Research Institute San Mateo, CA	 Roger S. Mazze, PhD Professeur invité Consultant indépendant Nanjing Medical University
 Donna Tomky, CNP, CDE Présidente sortante De l'AADE Infirmière Praticienne ABQ Health Partners			



Confidential ©Voluntis

The members are:

Dr Guillaume Charpentier

President and Founder of CERITD (Research Centre for the Intensification of the Treatment of Diabetes).

Professor Ananda Basu

Professor of Medicine, University of Virginia, Charlottesville, VA, USA.

Professor Rita Basu

Professor of Medicine, University of Virginia, Charlottesville, VA, USA.

Professor David Klonoff

Professor of Medicine at the University of California, Medical Director at DRI (Diabetes Research Institute) in San Mateo.

Roger S. Mazze, PhD

Independent consultant, non-tenured professor at the Nanjing University of Medicine in China

Dr Eugene Wright

Medical Director, Cape Fear Valley Medical Center, Fayetteville, North Carolina.

Dr Bernard Harris, Jr., MD, MBA, FACP

CEO Vesalius Ventures, Inc.

Athena Philis-Tsimikas, MD

Scripps Whittier Diabetes Institute, California.

Donna Tomky, C-NP, CDE

ABQ Health Partners, Albuquerque, New Mexico.

6.10.3.2 Oncology Scientific Advisory Committee

American Scientific Advisory Committee

Comité Scientifique en Oncologie, Etats-Unis



Dr Evan Ya-Wen Yu, MD

Seattle Cancer Care Alliance, Seattle, Washington.

April Boyd, BSN, RN, OCN

MD Anderson Physicians Network, Houston, Texas.

Joseph Kim, MD

Assistant Professor of Medicine, Yale University School of Medicine, New Haven, Connecticut.

Melissa Geller, MD, MS

Associate Professor, Gynaecologic Oncology, University of Minnesota, Minneapolis, Minnesota.

Sarah Porzig RN, BA, OCN

Director of Case Management, Fox Chase Cancer Center, Philadelphia, Pennsylvania.

Krystal Martin, RN, BSN

Barnes-Jewish hospital, Saint-Louis, Missouri.

Arvind Dasari, MD

Associate Professor, GI Medical Oncology, MD Anderson Cancer Center, Houston, Texas.

Debra Selm –Orr RN, MS, DNP, AOCN, CRNP

Doctor of Nursing Practice, Medical Oncology/Practice of Dr. Willis/Nurse Practitioner, Cancer Treatment Centers of America, Philadelphia, Pennsylvania

Prof Joseph Alvarnas, MD

City of Hope, Duarte, California

Wei Ai, PhD, MD

Assistant Clinical Professor, Department of Medicine, Haematology/Oncology, Stanford, USA

European Scientific Committee

Comité Scientifique en Oncologie, Europe



Pr Dame Lesley Fallowfield
(FMedSci, DPhil, BSc)
Pr de Psycho-Oncologie,
University of Sussex, Brighton, UK



Pr Karin Jordan,
Médecin chef de service
Hématologie et Oncologie
Université de Heidelberg
Allemagne



Pr Pere Gascón, MD, Pr
Chef du service d'Oncologie
coordonateur scientifique
Hôpital de Barcelone, Espagne



Dr. Matti Aapro
Doyen de l'Institut d'Oncologie
Membre du comité de Direction
Clinique de Genolier
Suisse




Pr Paolo Bossi,
Dr. Paolo Bossi
Oncologue médical spécialisé dans les
Cancers de la tête et du cou
Institut National du Cancer
Milan, Italie

Dr Matti S. Aapro

Genolier Clinic, Multidisciplinary Oncology Institute in Genolier, Switzerland

Prof Dr Karin Jordan

Department of Haematology and Oncology University Hospital Heidelberg, Germany

Prof Dame Lesley Fallowfield

*Professor of Psycho-Oncology at Sussex Health Outcomes Research & Education in Cancer,
University of Sussex, Brighton, United Kingdom*

Dr Paolo Bossi

Clinical Oncology Department, University of Brescia, Italy

Prof Dr Pere Gascon

Hospital Clinic, Barcelona, Spain - Medical Oncology Department

6.10.4 [Study list and references](#)

1) PDAPhone1 feasibility study

G. Charpentier. CERITD. Reported in the French ANAP Report "25 projets de télémédecine passés à la loupe" (A detailed look at 25 telemedicine projects) (2012).

2) PDAPhone2 feasibility study

Franco S, Dardari D, Boucherie B, et al. Real-life application and validation of flexible intensive insulin-therapy algorithms in type 1 diabetes patients. *Diabetes Metab* 2009;35:463-468.

3) Algorithmic and educational bases of functional insulin therapy

Howorka K, H. Thoma, H. Grillmayr , E. Kitzler. Phases of functional, near-normoglycaemic insulin substitution: what are computers good for in the rehabilitation process in type 1 (insulin-dependent) diabetes mellitus? Computed method programs Biomed 1990;32:319-23.

4) Telediab1 randomised clinical trial:

Charpentier G et al. The Diabeo Software Enabling Individualized Insulin Dose Adjustments Combined with telemedicine support improves HbA1c in Poorly Controlled Type1 Diabetic Patients. Diabetes Care 2011;34:533-539.

5) Telediab2 randomised clinical trial: NCT00937703

D Daoudi, M Joubert, S Franc, et al. Telediab2 study group A smartphone for the adjustment of basal insulin dose and for coaching: benefit in terms of glycemic control in patients with T2 diabetes Diabetologia EASD 2013, abstract 1061.

6) Telesage randomised clinical trial: NCT02287532

Evaluation of the DIABEO System in Poorly Controlled DM1 or DM2 Patients Treated With a Basal-bolus Insulin Regimen (TELESAGE).

7) eCO feasibility study

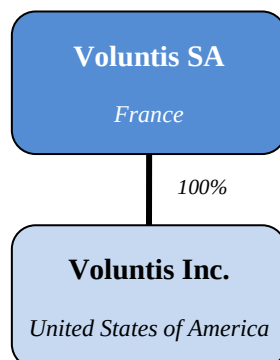
Liu JF, et al. Technology Applications: Use of Digital Health Technology to Enable Drug Development. JCO Clinical Cancer Informatics. 2018(2):1-12.

8) Randomised clinical trial to evaluate Zemy

Feasibility assessment of an e-health system (ZEMY) designed to manage symptoms in patients with breast cancer under anti-cancer treatment. Launch in 2018 to assess the clinical, organisational and economic benefits of the companion digital solution. End of study schedule for April 2019.

7. ORGANISATIONAL CHART

7.1 Group Organisation



7.2 List of subsidiaries, branches, and secondary establishments

The Company's head office is located at 58, Avenue de Wagram, 75017 Paris, France.

The principal establishment of the Company, registered with the Nanterre Commercial Court since 30 November 2004, is located at 22, Quai Gallieni, 92150 Suresnes, France, and includes all of the Company's direct operations.

The Company has no secondary establishment.

Moreover, the Company holds 100% of the share capital of its American subsidiary, Voluntis Inc., registered in the State of Delaware as number 73350928 and having its primary establishment at 125 Cambridge Park Drive Suite 304, Cambridge, MA 02142, USA. This subsidiary supports the parent company's development on the North American market. This support mainly covers commercial, medical and regulatory activities, as well as the local operational roll-out of partnerships.

The subsidiary posted 2018 revenues of €4,630,000, mainly generated with its parent company, resulting in 2018 net income of €184,000.

It has no debt other than its current account with the Company, totalling €1,893,000 as at 31 December 2018.

7.3 Principal intra-group flows

7.3.1 [International Sale Commission Agreement](#)

The Company directly markets its products and services in the United States of America. Nonetheless, with some of the Company's customers wanting to contract directly with its American subsidiary, Voluntis Inc., both of the Group's companies entered into a sales commission agreement on 1 April 2015, under which the American subsidiary markets and promotes the products and services in the North American territory in the Company's name and on its behalf. In return, Voluntis, Inc. is paid a commission based on a percentage of its sales.

7.3.2 [Service and Expertise Agreement](#)

Pursuant to a service agreement entered into between the Company and its American subsidiary on ^{1 April} 2015, Voluntis, Inc. provides the Company with services in connection with its business throughout North America (e.g. management of US accounts, compliance with regulatory processes of the Food and Drug Administration (FDA), medical expertise in diabetes and oncology). In return, Voluntis, Inc. is reimbursed for any costs reasonably incurred for services rendered, as well as a commission.

7.3.3 [Credit Facility Agreement](#)

In order to finance the activities of the American subsidiary, the Company and Voluntis Inc. entered into an agreement on April 1, 2015, for an indefinite period, for a current account advance of up to US\$2.0 million, bearing interest payable on January 1 of each year. At the date of the Registration Document, this current account is used for an amount of 1,711 KEuros.

8. PROPERTY, PLANT AND EQUIPMENT

8.1 Description of properties

The Company's head office is domiciled at 58, Avenue Wagram, 75017 Paris, France.

In addition, the Company leases 1,736 m² of office space at 22, Quai Gallieni, 92150 Suresnes, France.

Voluntis, Inc. leases approximately 190 m² (2,045 square feet) in office space at 125 Cambridge Park Drive Suite 304, Cambridge, MA 02142, USA.

Address	Lease type	Lease effective date	Expiration date	Annual rent (net of tax)
22, Quai Gallieni, 92150 Suresnes, France	Ten-year commercial lease of 1,630 m ² in office space.	1 April 2017	31 March 2017, with early exit option at the end of the 4 th and 7 th years.	€450,000
125 Cambridge Park Drive Suite 304, Cambridge, MA 02142, USA	5-year 4-month lease of 190 m ² of space	12 December 2016	11 April 2022	€85,000

The Company also occupies a temporary 41 m² (445 square feet) office space located at 125 Cambridge Park Drive, paying annual fees of 46,000 euros before tax.

8.2 Environmental issues

The nature of the Group's business does not entail any significant risks to the environment.

9. REVIEW OF THE FINANCIAL POSITION

9.1 Overview

Readers are invited to read the following information on the Group's financial position and results in conjunction with the consolidated financial statements prepared in accordance with IFRS for the years ended 31 December 2016 and 2017, included in section 20.1 of the base document registered by the AMF on 17 April 2018 under number I. 18-016, and with the consolidated financial statements prepared in accordance with IFRS for the year ended 31 December 2018, included in section 20.1 of the Reference Document.

9.1.1 [Consolidated financial statement](#)

The Group has prepared its consolidated financial statements for the financial year ended 31 December 2018 pursuant to IFRS, as adopted by the European Union.

The consolidated financial statements for financial years ended 31 December 2018 and 2017 were audited by the Company's Statutory Auditors, Ernst & Young et Autres for the 2017 and 2018 financial statements and RBB Business Advisors for the 2018 financial statements, following their appointment.

9.1.2 [Group Overview](#)

Created in 2001, the Group develops and markets innovative medical solutions, incorporating the latest information technology to improve treatment results and, more generally, the efficiency of healthcare systems.

By relying on investments in the technology platform, these patient-focused medical solutions distributed through long term partnerships with key players in healthcare combine the best of web and mobile technology, recognised expertise in the medical and regulatory field, and certified quality processes.

The Group consists of the parent company registered in Paris and a subsidiary incorporated in Delaware in 2010 and established in Cambridge (US), fully controlled by the Group. This latter is in charge of supporting business, medical, and regulatory activities for the North American market.

On the strength of the regulatory approvals of its therapeutic digital solutions in diabetes, the Company launched its product Insulia in the United States in late 2017 and in France in early 2018, concomitant with the launch of Diablo in France through the distribution partnership with Sanofi.

The Group's activity was financed mainly by:

- capital increases and convertible bond issues through three main private financing rounds since its creation for a total amount of €43.5 million;
- the funds raised during the Company's IPO on 29 May 2018 for a gross amount of €30.1 million;
- partnership agreements, having generated total pre-launch revenues of over €22 million;
- a line of credit with Kreos for a total amount of €7 million and
- the Research Tax Credit of €6.3 million paid to the Group.

The Group's operates as one operating single segment: "Development of therapeutic digital solutions based on its Theraxium platform".

9.1.3 [Main factors having an impact on business and results](#)

With regard to the stage of the Group's development, the main factors having an impact on the Company's results are:

- the signature of new partnership and distribution contracts for digital therapies developed by the Group and the swift deployment of these partnerships;
- the health insurers' ('payers') acquisition of and level of support for the solutions developed by the Group in the different areas where the product is marketable;
- the pace of development and the success of competing offers;
- the speed of patient inclusion under the distribution agreements or partnerships in place;
- the ambition of R&D programmes in their technical and clinical dimensions, and the speed of their implementation;
- the geographic concentration of business;
- the tension on the labour market and access to rare expert resources; and
- the existence of tax incentives for companies deploying research & development and innovation activities.

9.2 Financial position

9.2.1 [Comparison of financial statements for the financial years ended 31 December 2016 2017 and 31 December 2018](#)

In € thousands	Years ended December 31		
	2018	2017	2016
Revenue	4,533	7,302	10,272
Other operating revenue	637	1,095	987
Total operating revenue	5,170	8,396	11,258
Staff costs	(12,245)	(10,423)	(8,370)
Other operating income and expenses	(6,606)	(6,048)	(6,256)
Depreciation, amortisation & operating provisions	(1,827)	(1,550)	(970)
Operating income	(15,512)	(9,625)	(4,338)
Financial income	(427)	(423)	(472)
Taxes	3	22	(46)
Net income – Equity holders of the parent	(15,935)	(10,026)	(4,857)
EBITDA¹	(13,685)	(8,075)	(3,367)

¹ EBITDA (earnings before interest, taxes, depreciation, and amortisation) is a key indicator for the Group. It is defined as operating income excluding current and non-current depreciation, amortisation, impairment and provisions.

9.2.2 [Revenue and operating income from the 2017 and 2018 financial years](#)

The main revenue streams generated by the Group are :

- non-recurring revenue generated from items not requiring specific incremental effort. This category includes licensing revenues on existing products, upfront payments, milestones, and exclusivity fees;
- non-recurring revenue that requires the rendering of services. This category includes specific development services, setup and integration revenues, training performed; and
- regular or recurring revenue, which includes periodic licensing fees, Software as a Service (SaaS), and royalty proceeds.

According to this classification, the Group's revenue for the two featured financial years can be analysed as follows:

In € thousands	2018 (IFRS 15)	2017 (IAS 18)	2016 (IAS 18)	variation 2018-2017	variation 2017-2016
Upfront payment, exclusivity fees, perpetual licences	464	3 701	5 419	(3,237)	(1,718)
Development, set up and integration services	2,016	1,163	2,030	852	(867)
SaaS fees, royalties, maintenance & support	2,054	2,438	2,823	(384)	(385)
Total revenue	4,533	7,302	10,272	(2,769)	(2,970)

The change in revenue between the 2017 and 2018 financial years was due to the non-recurrent nature of the upfront payments for access to the technology, and of the milestones received for the diabetes solution distribution partnerships.

Due to the size of these partnerships, the Group notes a concentration of its revenue: three customers representing 78% and 75% of the Group's revenue for FY 2017 and FY 2018 respectively.

Revenues from development and integration grew significantly in 2018, due in particular to the application of the new revenue recognition standard. Based on a comparable methodology, integration and services revenue growth would have amounted to €193,000, plus the impact of IFRS 15 in an amount of €659,000. The delivery and transfer of control over applications developed under partnerships signed with the pharmaceutical industry account for most of these revenues.

€258,000 of the decrease in recurring revenue can be attributed to the Group's decision to move distribution of the historic patient relationship management (PRM) offer, a non-strategic development area, into indirect mode via an integration and distribution partner, and €216,000 to the end of the Telesage clinical trial.

The breakdown of the Group's income from the major therapeutic areas is as follows

In € thousands	2018 (IFRS 15)	2017 (IAS 18)	2016 (IAS 18)	variation 2018-2017	variation 2017-2016
Diabetes	1 159	4 141	6 655	(2 982)	(2 514)
Oncology	2 510	2 190	2 223	320	(33)
Other	865	971	1 394	(106)	(422)
Total revenue	4 533	7 302	10 272	(2 769)	(2 970)

Revenues from the diabetes product line reflect the decrease in the amount of upfront payments and regulatory milestones recorded in 2018 compared to the previous year, in line with the schedule for achieving these milestones and the terms of the contracts signed with pharmaceutical companies. They accounted for €3,500,000 in 2017, and totalled €308,000 in 2018.

The change in distribution method for PRM services mentioned above has impacted the contribution of Diabetes to revenue by €131,000 and other therapeutic areas by €127,000.

The contribution of the therapeutic areas beyond diabetes and oncology comes from the fulfilment of a contract in the haematology field (monitoring anticoagulant treatments) and the slowdown in the patient relationship management business.

Part of the Group's revenue is generated overseas, 39% of the amount in 2017 and 45% in 2018. The United States is the top contributor to international revenue, followed by Switzerland. The breakdown for the countries representing a significant part of the revenue is detailed below:

In € thousands	2018		2017		2016	
	Revenue	% of total	Revenue	% of total	Revenue	% of total
France	2,484	55%	4,419	61%	3,786	37%
USA	1,140	25%	1,976	27%	5,712	56%
Switzerland	827	18%	807	11%	-	-
Rest of world	82	2%	101	1%	773	7%
Total	4,533	100%	7,302	100%	10,272	100%

The revenue contribution by category and therapeutic areas is presented in the tables below:

In € thousands	2018 (IFRS 15)	Diabetes	Oncology	Other
Upfront payment, exclusivity fees, perpetual licences	464	308	96	60
Development, set up and integration services	2,016	557	1 140	319
SaaS fees, royalties, maintenance & support	2,054	294	1 273	487
Total revenue	4,533	1,159	2,510	865

In € thousands	2017 (IAS 18)	Diabetes	Oncology	Other
Upfront payment, exclusivity fees, perpetual licences	3,701	3,500	201	-
Development, set up and integration services	1,163	-	722	442
SaaS fees, royalties, maintenance & support	2,438	641	1,268	530
Total revenue	7,302	4,141	2,190	971

In € thousands	2016 (IAS 18)	Diabetes	Oncology	Other
Upfront payment, exclusivity fees, perpetual licences	5,419	5,178	241	-
Development, set up and integration services	2,030	701	779	550
SaaS fees, royalties, maintenance & support	2,823	776	1,204	844
Total revenue	10,272	6,655	2,223	1,394

For diabetes and the other therapeutic areas, the change in recurring revenue is due to the change in the method of marketing the PRM offer and the end of the Telesage clinical trial.

The change in the revenue recognition standard, with no material impact on total revenue for the year upon first-time application, explains a major portion of changes in revenue by type and therapeutic area, which can be summarised as follows in 2018:

impact of applying IAS 18 / IFRS 15	2018	Diabetes	Oncology	Other
Upfront payment, exclusivity fees, and perpetual licences	(477)	(192)	96	(381)
Development, set up and integration services	659	457	194	8
SaaS fees, royalties, maintenance & support	- 162	12	(188)	14
Total revenue	20	276	102	(359)

Other operating income, primarily comprising the research tax credit, for the portion of expenses recognised as operating expenses during the year, decreased from €1,078,000 in 2017 to €636,000 in 2018.

Operating expenses for 2016, 2017 and 2018

In € thousands	2018	2017	2016	variation 2018-2017	variation 2017-2016
Staff costs	12 245	10 423	8 370	1 822	2 053
Purchases & external expenses	6 606	5 764	6 002	842	46
Taxes & duties	311	284	254	27	30
Depreciation and amortisation, net	1 828	1 522	1 208	306	314
Provisions, net	(1)	28	(238)	(29)	(210)
Total operating expenses	20 989	18 021	15 596	2 968	2 709

The €2,684,000 increase in operating expenses between 2017 and 2018 reflects the Group's commitment to the continued technical, medical, and regulatory development of products, as well as to bringing the developed solutions to their markets in a number of regions.

Operating expenses and their development are itemised by component below.

9.2.2.1 Staff costs

In € thousands	2018	2017	2016
Wages	8,535	7,858	6,370
Payroll expenses	3,374	3,134	2,627
Share-based payments	613	351	522
Capitalised development costs	(1,396)	(920)	(1,150)
Cost of executing customer contracts	1,119		
Total personnel expenses	12,245	10,423	8,370
As a % of total operating expenses	59%	58%	54%

The increase in staff costs, the Group's largest expense, reflects the increase in average headcount from 103 to 107 employees year-on-year, up 3%.

Staff costs for 2018 also include exceptional items relating to the Company's IPO, estimated bonuses of €225,000 and changes to the governance structure, with the increase in the number of independent directors. Directors' compensation is set out in Section 15 of the Registration Document.

The Group has set up plans aiming to attract and retain key people and directors. In compliance with IFRS, an expense was recognised over the two financial years, to reflect the warrants and stock option plans for corporate officers and certain Group employees. This expense was measured using the Black

& Sholes method and spread over the time the beneficiary is required to be present at the Company in order to obtain the benefit of these awards.

9.2.2.2 Other operating costs

Changes and distribution of the Group's other expenses break down over the past two financial years, as follows:

In € thousands	2018	2017	2016
Purchases and other external expenses	4,887	4,152	4,005
Subcontracting purchases	2,465	2,294	2,722
Capitalised development costs	(745)	(682)	(725)
Purchases & external expenses	6,606	5,764	6,002
Taxes and duties	311	284	254
Total other operating costs	6,917	6,048	6,256
As a % of total operating expenses	33%	34%	40%

Occasionally, the Group uses external services providers to deliver specific production solutions or provide expertise, either for the development of projects sold to customers or for the development of its own products. The objective is to deliver on a tight deadline or consult with experts upon request. This offers flexibility for handling workload variations that are foreseeable in the medium term. Subcontracting expenses are the main item of other operating expenses, increasing from €2,294,000 in 2017 to €2,465,000 in 2018, up 7%.

Purchases and other external expenses increased significantly between the two years. In 2018, they were primarily composed of purchases of external services and fees (€1,301 k), telecommunications, network, and internet (€843 k), rents for main offices in France and the US (€592 k), and travel and transport costs (€853 k). The portion of external expenses incurred in the United States accounts for a significant portion of this increase (up 42% year-on-year).

9.2.2.3 Provisions and reversals

In € thousands	Exercices clos les 31 décembre		
	2018	2017	2016
Depreciation charge - intangible assets	1,571	1,184	948
Depreciation charge - tangible assets	257	338	260
Total net depreciation	1,828	1,522	1,208
Net provisions for contingent liabilities and expenses	(41)	21	(274)
Net pension provisions	40	7	48
Reversals of provisions on other current assets	-	-	(12)
Total net provisions	(1)	28	(238)
Total net reversals	1,827	1,550	970
As a % of total operating expenses	9%	9%	6%

Depreciation charges on intangible assets are essentially composed of capitalised development cost recovery of €1,571 k in 2018 and €1,160 k in 2017.

The rise in depreciation on tangible assets is directly related to the increase in tangible assets following the move of the Group's primary establishment to new facilities in Suresnes.

9.2.2.4 EBITDA

For the fiscal years presented, EBITDA was as follows :

In € thousands	Exercices clos les 31 décembre		
	2018	2017	2016
Operation income	(15,512)	(9,625)	(4,338)
Total net depreciation and amortization	1,828	1,522	1,208
Total net allocations to provisions	(1)	28	(238)
EBITDA	(13,685)	(8,075)	(3,367)

9.2.2.5 Research and Development Expenses

The Group allocates a significant portion of the operating expenses described above to Research and Development (R&D). These R&D costs mainly include personnel costs (excluding share-based payments), general resources used by the personnel (facilities, IT network, telecom), maintenance costs of the IT equipment used for R&D, and the cost of software development tools.

The R&D expenses presented below do not include expenses allocated to specific developments or support services provided to customers under a development or service contract, classified under cost of sales.

The Group capitalises a portion of these proprietary solution development costs.

R&D costs are booked net of subsidies received from various public bodies to fund certain R&D activities (essentially the Research Tax Credit, or RTC, in France).

In € thousands (except figures expressed as a %)	2018	2017	2016
Gross research and development costs	7,901	8,027	5,227
% of total revenue	174%	110%	59%
- Capitalised part of development costs	(2,141)	(1,602)	(1,875)
-Subsidies received (RTC, government support included in operation income)	(636)	(1 078)	(974)
Net R&D costs in reported operating income	5,124	5,347	2,378
Capitalised part of development costs	2,141	1,602	1,875
- Subsidies received (RTC deducted from capitalised R&D)	(1,155)	(605)	(697)
Capitalised development costs adjusted for subsidies received	986	997	1 178

The slight increase in the overall RTC recognised in 2017 and 2018 for €1,682,000 and €1,791,000 respectively, reflects the ongoing effort on R&D programmes over the financial years presented.

9.2.3 [Net income breakdown](#)

9.2.3.1 *Financial income*

In € thousands	2018	2017	2016
Financial costs	(568)	(588)	(788)
Financial income	141	165	316
Total financial income	(427)	(423)	(472)

The net financial expense came to €423,000 at 31 December 2017 and primarily comprises interest on convertible bonds issued in 2016 and 2017 and interest on the loan with Bpifrance Financement (see Note 5.8 to the consolidated financial statements).

The net financial expense amounted to €427,000 in 2018, including convertible bond issue charges until conversion of the 2017 CBs in May 2018 and interest charges on the Kreos bond issue as of its payment on 1 May 2018.

9.2.3.2 *Taxes*

Given the net operating losses accrued in recent financial years, the Group has not recorded any corporate income tax expense for the periods presented.

At 31 December 2018, the carry forward of unused tax credits held by the Group amounts to €56,377 k. The allocation of these losses will be capped at €1 million plus 50% of the portion of profits in excess of this cap.

Deferred tax assets are recognised for all unused tax losses to the extent that it is probable that taxable profit will be available against which the loss can be utilised. Under this principle, no deferred tax asset is booked in the Group's financial statements in excess of deferred tax liabilities.

9.2.4 [Net income and net earnings per share](#)

Net loss for the 2018 financial year was €15,935,000 compared to a loss of €10,026,000 in 2017.

This year-on-year change reflects the reduction in revenue recognised in the last financial year compared with the previous year of €2,769,000 for the reasons explained above, while the Group continues its efforts to develop and market solutions with operating expenses net of the subsidies obtained, up €3,119,000 year-on-year.

Basic earnings per share is calculated by dividing the net profit owed to the Group's shareholders by the weighted average number of shares (ordinary and preferred) in circulation during the financial year.

Earnings per share	2018	2017	2016
Weighted number of shares in circulation	6,435,057	4,656,274	4,083,484
Weighted number of diluted shares	7,317,082	5,724,923	5,399,279
Basic earnings per share (in €)	(2.48)	(2.15)	(1.19)

9.2.5 Presentation and analysis of the balance sheet at 31 December 2017 and 2018

In € thousands	Years ended December 31		
	2018	2017	2016
Assets			
Net intangible assets	1,901	2,489	2,676
Net tangible assets	563	764	277
Non-current financial assets	253	241	114
Other net non-current assets	1,016	-	-
Non-current assets	3,732	3,494	3,067
Trade and other receivables	1,505	299	3,435
Current financial assets	91		
Other current assets	5,445	2,322	2,257
Cash	19,783	1,845	5,831
Current assets	26,823	4,466	11,522
Total	30,555	7,960	14,589

	2018	2017	2016
Liabilities and shareholders' equity			
Shareholders' equity	17,301	(1,127)	2,096
Non-current financial debts	2,199	252	541
Non-current provisions and other non-current liabilities	3,419	463	452
Non-current liabilities	5,618	714	993
Current financial debts	1,440	4,003	6,467
Trade and other payables	6,196	4,370	5,033
Current liabilities	7,636	8,373	11,500
Shareholders' equity	30,555	7,960	14,589

9.2.5.1 Non-current assets

Acquisitions of intangible assets in the past two financial years primarily correspond to the capitalisation of software development costs incurred (meeting activation criteria), at €997,000 and €986,000 respectively in 2017 and 2018, to develop digital solutions in the fields of diabetes and oncology, and for the technology platform.

The transfer of the main Suresnes facility to new offices resulted in significant non-recurring investments in 2017, which were not repeated in 2018.

The adoption of IFRS 15 gave rise to the recognition of a non-current asset of €1,016,000 corresponding to the long-term amortisable value of the costs of performing contracts with customers. More detailed explanations can be found in the note dedicated to the transition to this new standard and in the reconciliation table presented in the 2018 consolidated financial statements.

9.2.5.2 Current assets

In € thousands	Years ended December 31		
	2018	2017	2016
Trade and other receivables	1,505	299	3,435
Other current assets	5,535	2,322	2,257
Cash and cash equivalents	19,783	1,845	5,831
Current assets	26,823	4,466	11,522

The change in net current assets was mainly due to the increase in cash and cash equivalents, provided by the capital increase carried out at the time of the Company's initial public offering and the bond issue subscribed to by Kreos.

The increase in other current assets reflects a €1,037,000 recognition of assets of the less than twelve-month portion of the costs of performing contracts with customers under IFRS 15, and the postponement of the payment of the RTC for 2017, which had not yet been settled as at 31 December 2018. The total RTC receivable from the French government amounted to €3,474,000 at year-end.

9.2.5.3 Shareholders' equity

As at 31 December 2018, Voluntis' share capital amounted to €757,566.10, divided into 7,575,661 ordinary shares, with a par value of €0.10 each.

Since its creation, the Group has set up several incentive plans in the form of founders' stock options, warrants, stock options and bonus shares awarded to executives and employees. Detailed information about these plans can be found in Section 4.4 of the Notes to the 2018 consolidated financial statements.

The evolution of consolidated equity over the period was as follows:

In € thousands	Years ended December 31	
	2018	2017
Shareholders' equity at 31 December 2017	(1 127)	2 096
Issue of share capital	34 880	6 301
Profit/(loss) of the year – 2018	(15 935)	(10 026)
Deferred tax provision	(24)	(1)
Share-based payments	613	351
Changeover to IFRS 15	(1 077)	-
Conversion reserve	(50)	152
Other	21	-
Shareholders' equity at 31 December 2018	17 301	(1 127)

9.2.5.4 Non-current liabilities and current liabilities

In € thousands	Years ended 31 December		
	2018	2017	2016
Non-current financial debts	2,199	252	541
Provisions	207	141	130
Other non-current liabilities	3,213	322	322
Non-current liabilities	5,618	714	993
Current financial debts	1,440	4,003	6,467
Provisions	77	77	-
Trade and other payables	2,062	1,492	1,788
Other current liabilities	4,057	2,801	3,244
Current liabilities	7,636	8,373	11,500

Details of the change in financial debt can be found in the Notes to the 2018 consolidated financial statements.

Non-current provisions include pension provisions, the amount of which is presented in the consolidated financial statements.

Other non-current liabilities consist of the portion of deferred income recognised at more than one year, which increased sharply following the application of IFRS 15, amounting to €3,213,000.

The "other creditors" item primarily includes short-term debt owed to third parties, tax and social security debts (employees and corporate bodies) as well as the non-current portion of deferred income, recognised under distribution partnership agreements, under product licences for which the transfer of control is and/or will be staggered in the future. These are up €1,017,000 due to the application of IFRS 15.

Other non-current liabilities mainly comprise the non-current portion of deferred income.

Financial debt underwent the following changes in the 2018 financial year:

In € thousands	2017	Increase	Repayment	Interest payment	Capitalised interest ⁽¹⁾	Conversion / reclassification on	2018
Convertible bond loans	3,715	7,550	(420)		162	(7,620)	3,387
Bank loans	370		(212)			93	252
Other loans	170		(170)			0	0
Loans	4,255	7,550	(802)		162	(7,527)	3,639
Bank borrowings and overdrafts	0						0
Interest-bearing loans	4,255	7,550	(802)		162	(7,527)	3,639

(1) including recognition of financial expenses calculated pursuant to IAS 32 for €121 k

Financial debt underwent the following changes in the 2017 financial year:

In € thousands	2016	Increase	Repayment	Interest payment	Capitalised interest ⁽¹⁾	Conversion / reclassification on	2017
Convertible bond loans	6,303	3,550			163	(6,302)	3,715
Bank loans	475		(170)		65		370
Other loans	224		(66)			13	170
Loans	7,002	3,550	(236)		229	(6,290)	4,255
Bank borrowings and overdrafts	6		(6)				0
Interest-bearing loans	7,008	3,550	(242)		229	(6,290)	4,255

(1) including recognition of financial expenses calculated pursuant to IAS 32 for €125 k

The Company had issued a convertible bond of a maximum amount of €7.1 million in June 2017, subscribed to in July 2017 and January 2018. Following the Company's initial public offering on the Euronext regulated market, on 31 May 2018 the Board of Directors recorded the automatic conversion of all the bonds into ordinary shares.

The Company also made a €7 million bond issue, subscribed to by Kreos, which is being drawn down in tranches. The repayment period is 36 months, and the contractual interest rate is 11%. Only tranche A was issued as at 30 December 2018 in the amount of €4 million. The issue is associated with the issuance of 70,000 warrants (BSAs) exercisable in proportion to the drawdowns on the bond debt.

With regard to trade payables, in accordance with the provisions of Articles L 441-6-1 and D 441-4 of the French Commercial Code, the breakdown of the balance of trade payables and receivables at the end of the last two financial years by maturity date was as follows:

Statement of trade payables		Invoices Not Due	Invoices received and due				Invoices overdue
			by less than 30 days	31-60 days	61-90 days	more than 91 days	
2018	Number of invoices concerned	56					104
	Total amount of invoices concerned (incl. VAT)	310,648	611,820	44,082	36,768	75,657	768,328
	Percentage of total purchases for the year (excl. VAT)	2.64%	5.19%	0.37%	0.31%	0.64%	6.52%
2017	Number of invoices concerned	61	-	-	-	-	85
	Total amount of invoices concerned (incl. VAT)	328,227	61,031	409	1,232	122,744	185,416
	Percentage of total purchases for the year (excl. VAT)	4.04%	0.75%	0.01%	0.02%	1.51%	2.28%

Statement of invoices issued		Invoices Not Due	Invoices issued and due				Invoices overdue
			by less than 30 days	31-60 days	61-90 days	more than 91 days	
2018	(A)	Issued invoices not paid at the closing date					
	Number of invoices concerned	6	22	5	1	2	30
	Total amount of invoices concerned (incl. VAT)	644,067	525,946	202,587	22	992	729,547
	Percentage of revenue for the year (excluding tax)	14.35%	11.72	4.52%	-	-	16.26%
	(B)	Invoices excluded from (A) relating to disputed claims					
	Number of invoices concerned					4	4
	Total amount of invoices concerned (incl. VAT)					70,375	70,375

2017	(A)	Issued invoices not paid at the closing date					
	Number of invoices concerned	0	-	-	-	-	3
	Total amount of invoices concerned (incl. VAT)	0	0	10,486	14,960	98,160	123,606
	Percentage of revenue for the year (excluding tax)	-	0.0%	0.14%	0.21%	1.35%	1.70%
	(B)	Invoices excluded from (A) relating to disputed claims					
	Number of invoices concerned	-				5	5
	Total amount of invoices concerned (incl. VAT)					72,283	72,283

9.2.6 [Proposed appropriation of income for 2018](#)

It is proposed that the loss for the year ended 31 December 2018, amounting to €13,899,076, be allocated in full to retained earnings.

It should be noted that the Company has not distributed any dividends in respect of the last three financial years.

9.2.7 [Non-deductible expenses](#)

In accordance with the provisions of Article 223 quater, the Company has not incurred any non-deductible expenses and charges referred to in Article 39-4 of this Code in respect of the financial statements for the financial year ended 31 December 2018.

10. CASH AND CAPITAL

See also Notes 5.5, 5.8 and 5.10 to the consolidated financial statements prepared under IFRS for the year ended 31 December 2018 in Section 20.1 of the Registration Document.

10.1 Capital, liquidity, and financing sources

Cash and cash equivalents include available cash and current financial instruments held by the Group, composed primarily of bank deposits. At 31 December 2018, cash and cash equivalents held by the Group stood at €16,144 k, compared to €2,410 k at end 2017. Analysis of net financial debt for the two featured years is presented below:

In € thousands	Years ended December 31	
	2018	2017
+ Non-current financial liabilities	2,199	252
+ Current financial liabilities	1,440	4,003
- Cash and cash equivalents	(19,783)	(1,845)
Total net debt	16,144	2,410

10.1.1 Capital and quasi-capital financing

Since the Company's creation it has received nearly €73.6 million (before deducting costs for capital increases) through the contribution of its founders and successive fundraising via conversions or repayments of bond instruments or capital increases in cash.

The table below summarises the capital increases in value until 31 December 2018.

Financing round	Date of payment	Total in € millions
2018	2018	30.1
2017	2017-2018	7.1
2014	2017	6.3
	2016	8.4
	2015	2.0
	2014	10.4
2011 – 2012	2012	2.0
	2011	3.1
2006 – 2008	2008	2.1
	2007	1.3
	2006	0.7
2001 – 2002	2001 - 2002	0.2
TOTAL CAPITAL INCREASES		73.6

10.1.2 [Financing through loans](#)

The Group has access to bank loans and borrowings to finance its operations. The financing structure as of 31 December 2018 is as follows:

- in 2014, the Group signed a zero-rate loan for innovation with Bpifrance Financement. €598 k of the initial €850 k was repaid at 31 December 2018, after a grace period. It appears in the IFRS consolidated financial statements in the amount of €252 k at end 2018; and
- In addition, under a Venture Loan Agreement and a Bond Issue Agreement entered into on 13 April 2018 between the Group and Kreos, the latter undertook to subscribe at latest on 1 May 2018 for bonds issued by the Company for a nominal amount of €4,000K. Two additional tranches of €1,500,000 may be issued at the Group's discretion until 13 April 2019, provided that certain conditions are met (see Section 22.7 of the Registration Document). Bonds are subject to a rate of 11% and are repayable each month over a 30 month period starting 6 months after each drawing. In consideration for these bonds, the Company allocated warrants to Kreos Capital V (Expert Fund) L.P (BSA 2018-Kreos).

Total loans still outstanding at 2018 stood at €3,639 k, of which a portion payable at less than one year (€1,440 k) and the balance (€2,199 k) at less than 5 years.

10.1.3 [Financing through loans since year-end](#)

Two additional tranches of the Venture Loan Agreement entered into on 13 April 2018 between the Company and Kreos were drawn down in a nominal amount of €3 million. Accordingly, all of the 2018-Kreos warrants, i.e. 70,000 warrants may be exercised as from the third drawdown (see Section 21.1.4.3 of the Registration Document).

Research Tax Credit

The Group receives a tax credit for a portion of the research expenses, repayable annually, due to the lack of taxable income and SME status as per the EU definition. (See Note 3.15.2 to the consolidated financial statements prepared under IFRS for the year ended 31 December 2018 in Section 20.1 of the Registration Document).

Repayment of the tax credit recognised in 2018, in the amount of €1,790 k, is expected over the second half of 2019.

10.2 Cash flow for the 2017 and 2018 financial years

Simplified cash flow statement (in € thousands)	Years ended 31 December		
	2018	2017	2016
Cash flow generated by operations	(14,726)	(5,396)	(4,610)
Cash flow from investing activities	(1,336)	(1,900)	(1,516)
Cash flow from financing activities	33,993	3,339	9,394
CHANGE IN CASH FLOW	17,931	(3,958)	3,269
Impact of exchange rate fluctuations	7	(24)	10
OPENING CASH BALANCE	1,845	5,824	2,545
CLOSING CASH BALANCE	19,783	1,845	5,824

10.2.1 [Net cash flows/\(used in\) operating activities](#)

Cash used in operating activities for the financial years ended 31 December 2017 and 2018 was €5.4 million and €14.7 million, respectively.

Cash consumption in 2018 was mainly due to the €15.5 million operating loss, driven by investments in technological and medical innovation and product marketing, as detailed in Section 9.

Working capital was relatively stable, despite the unfavourable impact of the deferral of the €1.7 million RTC payment.

10.2.2 [Net cash flows from/\(used in\) investing activities](#)

Investments in 2017 included a significant increase in the development and acquisition of property, plant and equipment as part of the relocation of the main Suresnes facility to new premises, which explains the decrease recorded in 2018.

Investment in intangible assets, through the capitalization of software development expenses, remained stable in 2018 compared to the previous year, at €1 million.

10.2.3 [Net cash flows from/\(used in\) financing activities](#)

Net cash from financing activities amounted to €34 million in 2018, mainly resulting from the capital increase following the initial public offering in May 2018 in an amount of €27.7 million, and to a lesser extent from the subscription of a tranche of convertible bonds (2017 convertible bonds) for an amount of €3.6 million and the issue of bonds subscribed by Kreos under a €4 million Venture loan agreement.

The repayment of financial debt (Kreos and Bpifrance) and corresponding interest represented a €1.2 million outflow in 2018.

10.3 Information on loan terms and financing structure

Information on the terms of the loans can be found in Note 5.8 to the consolidated financial statements prepared under IFRS for the financial year ended 31 December 2018, in Section 20.1 of the Registration Document, as well as, regarding the bond loan issued to Kreos, Section 22.7 of the Registration Document.

10.4 Restriction on the use of capital

For the setting up of a Venture Loan with Kreos (see Section 22.7 of the Registration Document), the Group pledged bank current accounts, which had a cumulative balance of €19.8 million at 31 December 2018, as collateral. This collateral gives Kreos the right to freeze the free cash flow on this account if the Group does not meet its commitments made under the Venture Loan, specifically in terms of repayment. As long as the Group meets its commitments, it is free to use the free cash flow in this account.

10.5 Financing sources required for the future

As of 31 December 2018, the amount of the Group's cash and cash equivalents was €19.8 million for a net cash flow used in operating activities and investments of €16.1 million for the 2018 financial year.

To finance the planned investments, the Group will rely on existing cash flow at end December 2018 and on:

- the additional drawdown of optional tranches of bonds with Kreos for a nominal amount of up to €3 million;
- repayment of the 2017 CIR and CII (French research and innovation tax credits), i.e. €3.6 million expected in February 2019 and September 2018 respectively; and

11. RESEARCH & DEVELOPMENT, PATENTS, LICENCES

11.1 Innovation policy

The Group's business is developing software solutions and platforms in the medical field to improve treatment effectiveness and patient care quality.

The goal of all actions taken by the Group's R&D department is to develop new, innovative solutions in this field.

The Group's R&D activities are focused on three main areas:

- development of finished products, targeting one pathology and one particular context. These finished products are medical devices for which the Group provides regulatory certifications for the countries in which they are intended for use. Next, these products are deployed either directly by the Group to patients and doctors in the target markets, or through partner companies in charge of distribution;
- development of an underlying IT platform, Theraxium, which is the basis for the finished products created by the Company (for more details on the Theraxium platform, see Section 6.6 of the Registration Document); and
- setting up of tools and methods specific to developing software with the status of a medical device, to build on the acquired expertise for industrialising practices within the Group.

The financial aspects of the R&D activities carried out during the past financial year are described in section 9.2.3.4. of the Registration Document).

Most of the software developments are carried out by Group employees or by service providers working in the technical environment and according to internal technical procedures.

The products' life cycle is controlled in a procedure defining each step of the design, specification, risk analysis, development, verification, and validation and delivery. The entire development process is encapsulated in a quality assurance system designed to guarantee the greatest product safety and reliability.

According to the intended use of the solutions developed, and the geography of the target markets, the solutions are submitted for regulatory approval in Europe and the United States based on the risk classification of the medical device in question. The Group thus has the EC marking and FDA clearance for its diabetes treatment solutions and plans to undertake approval procedures for its oncology products when the time comes.

The Group has adopted a protection policy for its expertise and software solutions, also filing for and obtaining patents.

The contracts entered into by the Company (see Section 11.4 and Chapter 22 of the Registration Document) are an essential component of the Research & Development policy and of capitalising on the Group's intellectual property.

11.2 Development costs

The Group owns the rights to various software applications and uses them directly or indirectly in its business.

The software incorporates the algorithms developed by the Group or digitised by the Group on the basis of algorithms that are public or that belong to customers and are then integrated into the therapeutic devices and companions marketed by the Group. The software is based partly on third party applications that allow certain functions of the Company's solutions (e.g. database, graphics) for which either the Company has the rights through a licensing contract with the owners of these solutions, or through open-source licences.

In France and the European Union, the software (source codes and documentation) is protected as such by copyright laws; the patent does not protect the software functions except in certain conditions.

Contrary to the patent, copyright is created without having to follow special formalities such as filing with an office. And so, in the European Union, the software is protected for a minimum of 50 years from its release date if it is original, and more specifically if it is the intellectual creation of its author. These criteria have been harmonised in the European Union since the Council's Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programmes.

Traditionally, the rights to software created by employees fall to the employer, except for contractual provisions more favourable to the employer, as per Article L. 113-9 of the French Intellectual Property Code.

In practice, the Group has completed various software filings with a solely evidentiary scope (*i.e.* to allow the Group to easily demonstrate that it had control of the software at a given moment). These filings are done via the French Software Protection Agency or the French National Industrial Property Institute by so-called "Soleau" filings.

The Company has made an evidentiary filing and/or owns the following software:

- Medpassport;
- Theraxium;
- Insulia; and
- eCO.

11.3 Patents and patent applications

11.3.1 [Overview](#)

The patents filed by the Company are meant to protect processes and software components that are original and specific to the development of software medical devices.

The policy for filing industrial property documents is aimed at creating a software asset database covering the key components of the solutions developed by the Company.

11.3.2 [As of the date of this Registration Document, the patents and patent applications used by the Group are those belonging to the Company.](#)

When applying for a patent, the Group files a French patent application (setting the priority date), and then within the priority period of 12 months, extends it abroad, benefiting from the priority period of twelve months internationally, by filing for an international patent application under the Patent Cooperation Treaty (PCT¹). The Group can, within a further 18 month period, file nationally and

¹PCT (*Patent Cooperation Treaty*) application: the PCT is a centralised filing system that covers a significant number of territories, simply, and as a precaution. The competent office for reviewing the PCT international application, the Swiss based World Intellectual Property Organisation (WIPO), searches for prior claims and sends the applicant the corresponding report along with a preliminary opinion on the patentability of the invention. At the end of the international phase of a PCT. application

(which generally lasts 30 months from the priority date), the countries/regions in which the application must actually be undertaken are chosen.

regionally, in select territories covering the countries in which it wishes to have protection.

In most countries, patents, once issued, are protected for twenty years from their filing date, unless yearly fees go unpaid or the patent is cancelled.

The Group's intended geographic coverage, i.e. the United States, Europe, and France is appropriate to its target markets.

11.3.3 [Details of the four patent families and patent applications](#)

Details of the various patent families and patent applications were established as of 7 February 2018.

First family: PROCESS AND SYSTEM FOR BUILDING A VIRTUAL PLATFORM INTENDED TO ALLOW OPERATORS TO EXCHANGE INFORMATION ON PATHOLOGY MANAGEMENT

This invention is a process for building a virtual platform to allow operators to exchange information on pathology management. The intended operators are patients, healthcare professionals, and manufacturers looking for or possessing data on pathology management. This invention is mobilised by the Theraxium platform and thus potentially implemented in all medical devices developed by the Group based on the platform.

This process includes:

- a measurement phase - measuring patients' information about pathology management;
- a collection phase - where information is collected from the various operators concerning the management of pathologies via a telephone network, and personal patient information relating to daily treatment follow-ups, and a health, fitness and sleep status assessment, with the process involving voice recognition of the operators;
- a storage phase - where the collected information is stored in a database;
- an information analysis phase - where information on pathology management is analysed; and
- a distribution phase - where analysed pathology management information is distributed to operators.

Thus, the platform's managers can adapt the platform's structure and content to the needs of the operators who consult it.

Country	Priority date	Filing date	Publication number	Issuance date	Expiry date	State
France		30 July 2002	2843215	10 February 2017	30 July 2022	Issued
PCT (International)	30 July 2002	28 July 2003	WO2004013798			The designation of EPO member countries was deemed to be withdrawn in 2005, and likewise for Japan in 2006. The Australian application (AU2003274297) is no longer in force.

There is only one French patent issued for this invention. The PCT procedure stopped at the application phase.

Second family: REMOTE MONITORING OF A SOFTWARE MEDICAL DEVICE: PROCESS AND SYSTEM

The purpose of the invention is a process for monitoring a medical device provided to a patient, comprising a communications terminal implementing software functionalities to accompany the patient in a predetermined treatment. This invention is mobilised by the Theraxium platform and thus potentially implemented in all medical devices developed by the Group based on the platform.

This process includes:

- a receiving phase: receiving current run data on the software functionalities originating in the medical device;
- a test phase: testing current data by comparison with baseline data according to at least one predetermined monitoring standard associated with a risk for the patient, where the risk is related to running the software functionalities with the current data; and
- a message phase: sending of an alert if such a risk is identified.

Country	Priority date	Filing date	Publication number	Issuance date	Expiry date	State
France		15 February 2013	3002346	6 March 2015	15 February 2033	Issued
PCT	15 February 2013	17 February 2014	WO201412523 5			Filed, entered into national phases in Europe (Application No. 14710022) and in the United States (Application No. US 14/766 138)

Third family: SECURE PRESCRIPTION FROM A SOFTWARE MEDICAL DEVICE

This invention is an information system that activates a software application, suitable for use on a software functionalities communications terminal, for accompanying a patient in a therapeutic treatment determined according to an electronic medical prescription including personal prescription data containing the information associated with the treatment prescribed to the patient. This invention is mobilised by the Theraxium platform and thus potentially implemented in all medical devices developed by the Group based on the platform.

This system comprises:

- a database storing said application and said electronic medical prescription;
- authentication methods that are suitable for cooperating with communications systems to authenticate the patient for said system using said communications terminal; and

- activation methods that are suitable for cooperating with communications systems to remotely activate said application and said prescription data on the communications terminal in order to authorise implementation of the software functionalities.

Country	Priority date	Filing date	Publication number	Issuance date	Expiry date	State
France		12 February 2015	3032815	30 March 2018	12 February 2035	Issued
PCT	12 February 2015	25 January 2016	WO2016128636			Filed (entry into national phases in the United States (Application No. US15/549 925) and in Europe (Application No. 16705234) with transmission by the EPO of an intention to grant)

Fourth family: BLOOD GLUCOSE MANAGEMENT IN A DIABETIC PATIENT

This invention is a medical device for managing the blood glucose level of a diabetic patient including:

- a memory module to memorise multiple blood glucose levels measured during a phase of balanced blood glucose over a set period of time, where said measured blood glucose levels are relative to a level of a blood component representing said patient's blood glucose level; and
- a treatment circuit implementing a management rule to detect a blood glucose imbalance in the patient by comparing said measured blood glucose levels with a range of threshold values showing an upper blood glucose limit corresponding to a hyperglycaemic state and a lower blood glucose limit corresponding to a hypoglycaemic state, where this circuit is furthermore configured to emit a warning signal when a blood glucose imbalance is detected.

This invention is built into the Insulia solution.

Country	Priority date	Filing date	Publication number	Issuance date	Expiry date	State
France		21 January 2016	3047098	25 May 2018	21 January 2036	Issued
PCT	21 January 2016	19 January 2017	WO2017125682			Filed (entry into national phases in the United States (Application No. US16/071824 - no limitation of claims) and in Europe (Application No. 17706543))

11.4 Partnership, research, service, and licensing contracts awarded by the Group or to the Group

11.4.1 Contracts in the field of diabetes treatment

On 29 July 2011, the Company entered into a partnership agreement with Sanofi-Aventis France and the French research centre for diabetes treatment intensification (“CERITD”) concerning “Diabeo”, a medical software device that uses components of the technology platform developed by the Group (see Section 22.2 of the Registration Document).

The Company also entered into a partnership with CERITD. The purpose of this contract is to specify the conditions and procedures of the partnership between the parties for the development, release and marketing of Diabeo software or another telemedicine solution, in France or abroad.

This contract is part of a partnership begun with CERITD in 2009. As such, CERITD developed algorithms and the formalisation of methods; the Diabeo software was then developed by the Group.

The contract has a term of five years and entered into effect on 1 February 2015. It can be cancelled in the event of a breach by either party.

It provides a preferential right, in certain conditions, for CERITD to consider developing a solution different from Diabeo in the field of diabetology with the Company.

The contract is also aimed at providing the procedures for compensating CERITD for marketing the solutions abroad.

In 2016, the Company entered into a non-exclusive licensing contract with Sanofi SA for the “Insulia” medical device (see Section 22.3 of the Registration Document).

Finally, the Company entered into a non-exclusive licensing and partnership contract with Verily to allow the marketing of some of the solutions developed by the Group, including Insulia, within the platform developed by Verily (see Section 22.4 of the Registration Document).

11.4.2 Other contracts (licensing and partnership)

In October 2015, the Company entered into a development and licensing contract with Roche SA that led to the development of a specific solution based on algorithms developed by Roche, dedicated to supporting women with breast cancer (see Section 22.1 of the Registration Document). Based on the Theraxium Oncology platform, for which a usage licence was granted to Roche. The solution has been extended to cover multiple cancers under a new contract signed in 2018. Specific solutions have been developed and delivered to Roche, who is the owner. Roche terminated the partnership in 2019.

At the end of 2015, the Company entered into a partnership agreement with AstraZeneca UK Limited, leading to the development of a software application dedicated to monitoring women with ovarian cancer (see Section 22.1 of the Registration Document). The technology solution in development is the property of Voluntis.

11.5 Trademarks and domain names

11.5.1 Trademarks

The Company holds various trademarks in France, with the European Intellectual Property Office (unit coverage in European Union countries) and international filings (that may name different countries or geographic areas) or national filings (in Canada).

The trademark is a sign designating products and/or services inventoried by class.

The Group strives to designate products and services that match its activity as well as provide protection on its key markets.

As with patents, the Group is assisted by an industrial property consulting firm.

In most countries, a trademark is valid for ten years from its filing and may be renewed as many times as its bearer wishes. The right to the trademark, which is conditional on its genuine use, its defence against third parties, and its lack of expiry, is therefore potentially perpetual.

Trademarks	Country	Classes	Date of filing or territorial expansion or renewal	Number of filing, registration or territorial expansion or renewal	Application status
 <i>Passeport Médical</i>	France	9 ; 38 ; 42	14/02/2001 (renewed in 2011)	3082866	Registered
 <i>Passeport Santé</i>	France	9 ; 38 ; 42	14/02/2001 (renewed in 2011)	3082864	Registered
 VOLUNTIS	France	9 ; 35 ; 38 ; 41 ; 42	14/02/2001 (renewed in 2011)	3082865	Registered
MEDPASSPORT	France	9 ; 35 ; 38 ; 41 ; 42	31/01/2002 (renewed in 2011)	3144747	Registered
MEDPASSPORT	EU	9 ; 35 ; 38 ; 42	25/11/2004 (renewed in 2014)	4135951	Registered
VOLUNTIS	France	9 ; 38 ; 41 ; 42	17/11/2009	3691700	Registered
VOLUNTIS	INTERNATIONAL (EU, UNITED STATES, Canada)	9 ; 38 ; 41 ; 42	01/12/2009 (under priority of French trademark at 17/11/2009)	1029737	Registered in the United States in classes 9 and 42 after limitation Registered in the EU
VOLUNTIS	CANADA	9 ; 38 ; 41 ; 42	04/05/2010 (under priority of French trademark at 17/11/2009)	TMA828554	Registered

Trademarks	Country	Classes	Date of filing or territorial expansion or renewal	Number of filing, registration or territorial expansion or renewal	Application status
TENSEO	EU	9 ; 10 ; 38 ; 42 ; 44	16/12/2011	10502458	Registered after changes made in response to opposition proceedings (closed)
CONNECTED THERAPEUTICS	France	9 ; 10 ; 38 ; 42 ; 44	01/02/2012	3893610	Registered
CONNECTED THERAPEUTICS	INTERNATIONAL (EU)	9 ; 10 ; 38 ; 42 ; 44	27/02/2012 (under priority of French trademark at 1/2/2012)	1110891	Registered in the EU
INSULIA	France	9 ; 10 ; 38 ; 42 ; 44	31/10/2012	3957599	Registered
INSULIA	INTERNATIONAL (EU, UNITED STATES)	9 ; 10 ; 38 ; 42 ; 44	25/3/2013 (under priority of French trademark at 31/10/2012)	1163996	Registered in the United States after limitation Registered in the EU after limitation
THERAXIUM	France	9 ; 35 ; 42	06/06/2013	4010175	Registered
THERAXIUM	INTERNATIONAL (EU, UNITED STATES)	9 ; 35 ; 42	22/05/2014	1214544	Registered in the United States after limitation Registered in the EU
TELEDIAB	France	9 ; 38 ; 42 ; 44	17/05/2018	4454026	Registered Co-owned by Voluntis and CERITD

It is specified that the "DIABEO" trademark was assigned by the Company to Sanofi-Aventis France under the eponymous partnership. Therefore, the trademark is used by the Group under a licence.

11.5.2 [Domain names](#)

Since its creation, the Group has filed several domain names, including the following:

connectedtherapeutics.com	insulia.fr	tenseo.fr
connected-therapeutics.com	breezea.com	tenseo.com
voluntis.com	insulia.eu	theraxium.fr
voluntis.fr	medpassport.com	theraxium.com

11.6 Intellectual property rights pledged

Under an intellectual property pledge agreement entered into on 13 April 2018 between Kreos and the Company, this latter pledged Kreos the following rights to guarantee the sums owed for the bond loan subscribed by Kreos:

- its software Mepassport, Theraxium, Insulia and eCo;
- patents listed in Section 11.3 of the Registration Document;
- brands listed in Section 11.5.1 of the Registration Document with the exception of the Canadian brand Voluntis, with the specification that pledging of the brands Passeport Médical, Passeport Santé, Medpassport, and Tenseo, which are not being used as of the date of this Registration Document, will only be registered by Kreos if the Company actually uses them;
- the domain names listed in Section 11.5.2 of the Registration Document, except for breezea.com, tenseo.fr and tenseo.com;
- and any similar right that becomes Company property in the future.

12. TRENDS

12.1 Key trends since the end of the last financial year ended 31 December 2018

In the United States, the Group is continuing its direct strategy with the paying entities, based on a value proposition reinforced by the first real-life usage data and its practical experience in deploying its Insulia solution. The expansion of its direct sales team continued, resulting in new hires in the sales, marketing and medical fields.

In oncology, the Group is continuing its work with existing customers to extend the partnerships launched several years ago, and intends to file a regulatory clearance application with the FDA for its multi-cancer monitoring solution, with the goal of obtaining approval before the end of 2019.

In diabetes, the Group obtained the EC marking for the new version of Insulia, which incorporates intermediate-acting Neutral Protamine Hagedorn (NPH) insulin.

Furthermore, at the Company's request, on 11 April 2019 Kreos subscribed to two additional tranches of bonds for a total amount of €3 million, bringing the total amount of the bond issue to €7 million.

Finally, as part of the Digital Therapeutics Alliance, the Group contributes to sector-led initiatives to promote the use of Digital Therapies within patient care.

12.2 Known trend, uncertainty, request for commitment, or event reasonably likely to influence the Group's prospects

On 21 March 2019¹, the Group updated its medium-term objectives, given the moderate pace of integration of digital therapies into healthcare professionals' operational processes in 2018 and the termination of a partnership agreement in oncology. It now aims to meet the following targets over the coming years:

- at least €40 million in revenue by 2021 (compared to €50 million initially), primarily composed of recurrent post-launch revenues; The Diabetes product line must represent 70% of its revenues, with the remaining 30% being generated by oncology and other therapeutic areas; and
- achievement of positive² EBITDA during the 2021 financial year (target initially to be reached by 2020).

For the same reasons, the Group no longer expects a balanced breakdown of its post-launch revenues between direct and indirect marketing, nor the achievement by 2021 of more than 160,000 active users of its diabetes and oncology solutions.

¹ See the press release on the Company's 2018 annual results, published on the same date.

² L'EBITDA (earnings before interest, taxes, depreciation, and amortisation) is a key indicator for the Group.

13. PROFIT FORECASTS OR ESTIMATES

The Company does not intend to forecast or estimate profits.

14. ADMINISTRATIVE, MANAGEMENT, SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT

Prior to the General Meeting of shareholders held on 11 April 2018, the Company was constituted as a French *société anonyme* with a management board and a supervisory board

This General Meeting approved the change in the Company's administrative and management mode by adopting a structure with a Board of Directors and also adopted new rules of governance. At their meeting held on 11 April 2018, the Board of Directors opted to separate the positions of Chairman of the Board and Chief Executive Officer.

Its Articles of Association were also amended as part of its initial public offering on the Euronext regulated market in Paris. A summary description of the main provisions of the Company's Articles of Association can be found in Section 21.2 of the Registration Document.

14.1 Officers and member of the Board of Directors

14.1.1 [Management](#)

As of the date of this Registration Document, the Company's management is composed as follows:

Name	Office	Main operational functions in the Company	Main operational functions outside the Company	Start and end of appointment
Pierre Leurent	Chief Executive officer	Chief Executive officer	Non applicable	<u>First appointment:</u> Board of Directors' meeting of 11 April 2018. <u>Expiry date:</u> on the expiry date of his position as member of the Board of Directors
Romain Marmot	Deputy Chief Executive Officer	Chief US Operations Officer	Non applicable	<u>First appointment:</u> Board of Directors' meeting of 11 April 2018. <u>Expiry date:</u> on the expiry date of the CEO's appointment
Alexandre Capet	Deputy Chief Executive Officer	Global Chief Operations Officer	Non applicable	<u>First appointment:</u> Board of Directors' meeting of 11 April 2018. <u>Expiry date:</u> on the expiry date of the CEO's appointment

Management use the Company's head office as their professional address.

Their management expertise and experience come from the different employee and management positions they have previously held (see Section 14.1.3 of the Registration Document).

14.1.2 Board of Directors

As of the date of this Registration Document, the Board of Directors is composed as follows:

Name	Office	Main operational functions in the Company	Main operational functions outside the Company	Start and end of appointment
Eric Elliott	Chairman of the Board of Directors	Non applicable	Chairman of the Board of Directors of WellDyneRx	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Pierre Leurent	Director	Chief Executive officer	Non applicable	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Bpifrance Participations represented by Laurent Higuieret	Director	Non applicable	Investment Director Healthcare & Life Science at Bpifrance Large Venture Fund	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020. <u>Change of permanent representative:</u> as of 10 January 2019, Laurent Higuieret replaced Jean Bertin as the permanent representative of Bpifrance Participations
LBO France Gestion represented by Franck Noiret	Director	Non applicable	Managing Director of Innovation Capital	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Nicolas Cartier*	Director	Non applicable	Member of the Executive Committee of BioMerieux	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.

Name	Office	Main operational functions in the Company	Main operational functions outside the Company	Start and end of appointment
Viviane Monges*	Director	Non applicable	Non applicable	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Jan Berger*	Director	Non applicable	Chief Executive Officer, Health Intelligence Partners	<u>First appointment:</u> General Shareholders' Meeting of 25 October 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Roberta Herman*	Director	Non applicable	Non applicable	<u>First appointment:</u> co-opted during the Board of Directors' meeting held on 25 October 2018 to replace CM-CIC Innovation, subject to ratification at the next General Shareholders' Meeting (to be convened on 24 May 2019) <u>Expiry date:</u> following the General Meeting of shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.
Vesalius Biocapital II represented by Alain Parthoens	Observer	Non applicable	Managing Partner of Vesalius Biocapital	<u>First appointment:</u> General Shareholders' Meeting of 11 April 2018 <u>Expiry date:</u> following the General Meeting of Shareholders convened to vote on the financial statements for the financial year ending 31 December 2020.

* *Independent Director*

Those legal entities that are members of the Board of Directors use their respective home office as a business address, and natural persons use the Company's home office.

The management expertise and experience of the members of the Board of Directors come from the different employee and management positions they have previously held (see Section 14.1.3 of the Registration Document).

14.1.3 [Other corporate offices](#)

Other corporate offices currently held outside the Company

Name	Office	Company
Management		
Pierre Leurent	Chairman Director	Voluntis Inc. Digital Therapeutics Alliance
Romain Marmot	Secretary	Voluntis Inc.
Alexandre Capet	Non applicable	Non applicable
Board of Directors		
Eric Elliott	Chairman of the Board of Directors	WellDyneRx
Bpifrance Participations represented by Laurent Higuieret	<u>In his own name:</u> Observer Observer <u>As representative of Bpifrance Participations:</u> Observer	Enyo Pharma Gensight Biologics Poxel
LBO France Gestion represented by Franck Noiret	<u>In his own name:</u> Observer Member of the Board of Directors <u>As representative of LBO France Gestion:</u> Director Board Member	Ekinops* Zesty Limited Entrepreneurs & Investisseurs Technologies Kayentis
Nicolas Cartier	Non applicable	Non applicable
Viviane Monges	<u>In his own name:</u> Director Director Director Member of the Strategy Committee	UCB Novo Holding Idorsia Néomedlight
Jan Berger	<u>In his own name:</u> Director Director Director Director Director	GNS Healthcare Accentcare Cabia Health Solutions UCB Tabula Rasa
Roberta Herman	<u>In his own name:</u> Member of the Board of Trustees	Joslin Center for Diabetes
Vesalius Biocapital II represented by Alain Parthoens	<u>In his own name:</u> Officer Officer	A Q Invest BVBA A Q Partners BVBA

Name	Office	Company
	<u>As representative of Vesalius Biocapital II:</u> Director <u>As representative of A Q Invest BVBA:</u> Director Director Director Director Managing Partner Managing Partner Managing Partner	Bienca NV NCARDIA S.A. Promethera Biosciences S.A. Epics Therapeutics S.A. Acticor Biotech Newton Biocapital Partners SPRL Vesalius Biocapital II Partners S.àr.L. Vesalius Biocapital Partners S.àr.l

* *Company whose shares are admitted for trading on the Euronext regulated market in Paris*

Other positions held during the past five financial years and now ended

Name	Office	Company
Management		
Pierre Leurent	Member of the Board of Directors	Syntec Numérique
Romain Marmot	Non applicable	Non applicable
Alexandre Capet	Non applicable	Non applicable
Board of Directors		
Eric Elliott	Chairman and Chief Executive Officer Member of the Board of Directors	Prime Therapeutics LLC Main Street America LLC
Bpifrance Participations represented by Laurent Higuieret	<u>In his own name:</u> Director Observer Observer Director	Biom'Up H4D TxCell Poxel
LBO France Gestion represented by Franck Noiret	<u>In his own name:</u> Vice-Chairman of the Supervisory Board Member of the Board of Directors Member of the Board of Directors <u>As representative of LBO France Gestion⁽¹⁾:</u> Director Director Member of the Supervisory Board	Tronic's Microsystems** Omni Orthopaedics, Inc. Omni Life Science, Inc. Genoway** Maeglin Software Tronic's Microsystems**
Nicolas Cartier	Non applicable	Non applicable
Viviane Monges	Non applicable	Non applicable
Jan Berger	Non applicable	Non applicable

Name	Office	Company
Roberta Herman	<u>In his own name:</u> Chief Operations Officer Director	Harvard Pilgrim Healthcare Planned Parenthood of Massachusetts
Vesalius Biocapital II represented by Alain Parthoens	<u>As representative of A Q Invest BVBA:</u> Director Director Director <u>As representative of A Q Promethera Biosciences:</u> Member of the Supervisory Board	Ogeda Profibrix Bio-Sourcing SISE

* *Company whose shares are admitted for trading on the Euronext regulated market in Paris*

* *Company whose shares are admitted for trading on Euronext Growth in Paris*

(&) *or the management company Innovation Capital that was the subject of a universal transfer of assets to LBO France Gestion, effective as of 31 October 2016.*

14.1.4 [Statements about management and members of the Board of Directors](#)

To the Company's knowledge, there are no family ties between the natural persons listed above.

To the Company's knowledge, in the past five years, none of these natural persons has:

- been convicted of any fraud;
- been associated in their capacity as executive or director or member of a supervisory board with any bankruptcy, receivership or liquidation¹;
- been prevented by any court from acting as an executive officer, a director or a member of a supervisory body of an issuer or from being involved in the management or business conduct of an issuer;
- been convicted of any official public crimes or sanctions by any statutory or regulatory authorities (including designated professional organisations).

¹ With the exception of Franck Noiret, in his capacity as permanent representative of Innovation Capital, director of (i) Maeglin Software, in respect of the opening of the court ordered liquidation of the company on 4 July 2016 by the Montpellier Commercial Court, and (ii) Iwedia, in respect of the closure of the court ordered liquidation of the company ordered on 14 September 2015 by the Rennes Commercial Court.

14.1.5 [Profiles of members of management and the Board of Directors](#)

Management

Pierre Leurent – Chief Executive Officer and Director, French national, 41 years old.



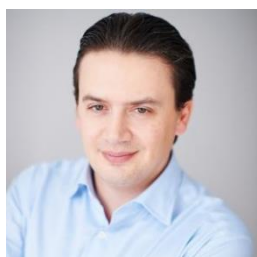
Pierre has 20 years of digital health experience in Europe and the United States. Before founding Voluntis, Pierre worked in the Medical Imaging Division of General Electric Medical Systems Europe and then with HealthCenter Internet Services in San Francisco, where he helped develop online cardiology EMR solutions.

In addition to his roles at Voluntis, Pierre is also Chairman of the Healthcare Committee of Syntec Numérique, General Coordinator of Alliance eHealth France (which includes LEEM, LESISS, SNITEM, and Syntec Numérique), Co-chair of the Efficiency Working Group of the French Healthcare Strategic Committee (CSF Santé), Steering Committee member of the Medef Healthcare Business Committee, and an Ambassador of French Tech's Healthtech Thematic Network.

In the United States, where he has lived since mid-2017, Pierre is Chairman of the Digital Therapeutics Alliance.

Pierre is a graduate of the Ecole Centrale Paris engineering school.

Romain Marmot – Deputy Chief Executive Officer, French national, 40 years old.



Romain has more than 15 years of experience in digital healthcare and software medical devices.

For over 12 years, he directed research & development and then industrial operations at the Company. In 2014, Romain moved to Cambridge, Massachusetts to oversee Voluntis' operations in North America.

Romain is a Foreign Trade Advisor for France, for which he has headed the Boston-New England Committee since 2018.

Romain is a graduate of the Ecole Centrale Paris engineering school.

Alexandre Capet – Deputy Chief Executive Officer, French national, 46 years old.



Before joining Voluntis in 2012, Alexandre worked for 15 years in the pharmaceutical industry. He held positions of increasing responsibility at Sanofi, where he was Director of Strategic Planning for the Group, then Director of M&A and Diversification in France. As such, he played a large role in developing the three-way partnership on Diabeo with Sanofi, CERITD, and Voluntis.

Alexandre Capet is a graduate of HEC and the Institut d'Etudes Politiques de Paris. He also holds a master's degree in health economics from Paris-Dauphine University.

Board of Directors

Eric Elliott – Chairman of the Board of Directors, US national, 55 years old.



In his most recent roles as Prime Therapeutics' Chairman and Chief Executive Officer, Eric Elliott was responsible for all operating and strategic aspects of the full service pharmacy benefit management company. With approximately \$17 billion in annualised drug spend under management, Prime Therapeutics is the fourth largest pharmacy benefit manager in the United States, servicing 23 health plans, other smaller pharmacy benefit managers (PBMs), and employer direct customers.

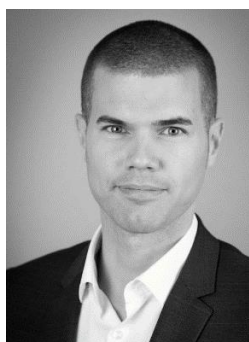
Eric was critical to the success of Prime Therapeutics. Eric led the partnership with Blue Cross and Blue Shield Plans to ensure members receive the highest quality of care while managing appropriate pharmaceutical costs and trends. Under Eric's leadership, Prime was recognised locally and nationally by prominent publications and organisations for its employee engagement, healthy workplace, as well as the highest quality and care of service for members, and business growth.

With experience running three integrated PBMs, Eric is skilled in leading and growing businesses to include product line extensions and new segments. He previously served as President at Cigna's Pharmacy Management and has held senior executive level positions at Aetna, PCS HealthSystems, and Rite Aid Corporation.

Eric has served for many years on the board of directors at Prime, The Main Street America Group, the Pharmaceutical Care Management Association and the Twin Cities American Heart Association. Elliott also serves on The Wall Street Journal CEO Council.

Eric received his bachelor's degree in management and finance, and a Master of Business Administration from Temple University in Philadelphia.

Laurent Higuieret – Permanent representative of Bpifrance Participations, Director, French national, 40 years old.



Laurent is an investment manager within the Large Venture fund at Bpifrance, in charge of investments in the field of health and life sciences. He currently chairs the Voluntis (digital therapies) Board of Directors and previously chaired those of Biom'Up (biosurgery) and Poxel (diabetes). Laurent is also an observer on the Board of Directors at Enyo Pharma (VHB, NASH) and GenSight Biologics (gene therapy) and monitors the investments of Bpifrance Participations in DBV Technologies (food allergies) and MedDay Pharmaceuticals (neurometabolic diseases).

Before joining Bpifrance in 2014, he worked at the BNP Paribas Group for six years mainly as an investment banker in the M&A Health team.

Laurent Higuieret has a PhD in Pharmacy from the University of Bordeaux and a Master in Finance from EM Lyon Business School.

Franck Noiret – Permanent representative of LBO France Gestion, Director, French national, 53 years old.



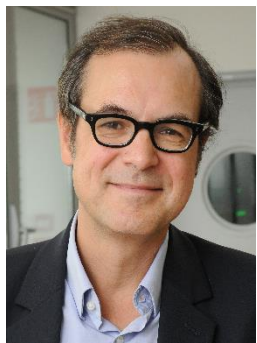
Franck Noiret is Managing Director of Innovation Capital at LBO France, a leading private equity firm with over 3 billion euros under management. He joined Innovation Capital in 2005 as General Partner, and LBO France in 2016 when the firms joined forces. He is currently investing in Digital Health companies in Europe through the Services Innovants Santé et Autonomie (SISA) fund.

With over 20 years of investment experience in Technology and Healthcare, Franck Noiret is currently a Board member of Voluntis, Entrepreneurs & Investisseurs Technologies, Kayentis, Omni Orthopaedics (US), Zesty (UK) and Observer at Ekinops (listed on the regulated market of Euronext Paris). He has also carried out many industrial sales and IPOs including Arkadin (acquired by Ardian), Esterel Technologies (acquired by Ansys), Golden Telecom (listed on the NASDAQ, acquired by Vimpelcom), Highdeal (acquired by SAP), Travelprice.com (acquired by Lastminute.com), Tronic's Microsystems (listed on the regulated market of Euronext Paris, acquired by TDK), and Valoris (acquired by Sopra).

Prior to joining Innovation Capital, Franck Noiret was Director at Apax Partners in Paris, one of the leaders in private equity in Europe with several billion euros under management, where he was responsible for investments in Technology and Telecoms ranging from venture capital to growth LBO. From 1995 to 2000, Franck Noiret was Principal Banker at the European Bank for Reconstruction and Development (EBRD) where he was responsible for private and public sector investment projects in Central and Eastern Europe. In these positions, he also served as a transition and privatisation advisor to certain governments and operators in the region. De 1989 à 1993, Franck Noiret was a banker in the City of London for Société Générale after starting his career as an auditor at Arthur Andersen in Paris.

Franck Noiret holds an MBA from the Wharton School at the University of Pennsylvania (US) and a master's degree in Corporate Finance from Paris-Dauphine University. He graduated with the highest distinction from Sciences Po Paris.

Nicolas Cartier – Director, French national, 52 years old.

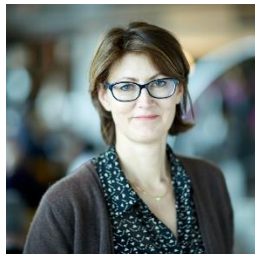


Nicolas Cartier is Vice President of bioMérieux's Industrial Microbiology Unit and member of bioMérieux's Executive Committee.

Before joining bioMérieux, Nicolas was Chief executive officer of Sanofi France from 2009 to 2013. Prior to that, he held various internal positions within Sanofi, in particular in Thailand, where he was in charge of commercial development for the Southeast Asia region within the Animal Health Division; in Shanghai, where he headed up Sanofi China's Pharmaceutical Division; and in Mexico City, where he was Chief executive officer of Sanofi Mexico. In addition, Nicolas was Chief of Staff of the Chairman and CEO of Sanofi.

Nicolas is a graduate of École Polytechnique, École des Ponts and Institut d'Études Politiques de Paris.

Viviane Monges – Director, French national, 55 years old.



Viviane Monges has 30 years of experience as a Senior Executive in the finance function. She has had a successful career in international companies, holding positions in Europe, Asia and the United States, mostly in the healthcare sector.

After five years at Agence France Presse in Paris and then Hong Kong, she joined the pharmaceutical industry with Wyeth, first in the French subsidiary as director of management control, then at the Group's head office in Philadelphia, as Chief Financial Officer of the Europe Region, then of the Pharma Business Unit (USD 6 billion). She took an active role in many projects to transform the company, organisationally, strategically and in mergers & acquisitions and to establish the Sarbanes-Oxley rules on internal control.

In 2006, Viviane joined the OTC Division at Novartis as Chief Financial Officer, Europe. She took part in many key projects, including a reorganisation of the Europe Region as well as the establishment of shared service centres. Next, she served as Global CFO of the OTC Division based in the United States (USD 3.5 billion) during the Prevacid launch.

In 2010, Viviane was appointed CFO of Galderma, a Swiss pharmaceutical group specialised in dermatology (USD 2.5 billion). This group, a joint venture of Nestlé and L'Oréal, is an industry leader in Rx, OTC, and Aesthetics. In 2014, following Nestlé's acquisition of all of Galderma's shares, the latter became Nestlé Skin Health. In 2015, Viviane joined Nestlé as CFO of the Business Excellence Department, which groups together the worldwide support functions (finance, HR, IT, procurement, digital and property). For three years, Viviane has been responsible for a major programme to transform the Group.

In 2018, Viviane decided to focus on directorship. She is a member of the board of directors of UCB and Novo Holdings.

Viviane is a graduate of ESCP, a French national, and a resident of Lausanne.

Jan Berger– Director, US national, 61 years.



Residing in the United States, Jan Berger has over 30 years' experience in the private and public healthcare sectors.

In 2009, Jan Berger founded Health Intelligence Partners, a consulting firm operating in 14 countries that helps its healthcare clients to execute their development strategies.

She has previously led a number of large-scale projects, and sat on multiple Boards of Directors, in particular as Chief Medical Officer and Chief Innovation Officer at CVS Health / Caremark in the United States.

As a result, she has an extensive network of American payers and has acquired a deep understanding of their challenges and operations.

She holds a PhD in Medicine, a Master's degree in law and a Certificate of Medical Business Administration,

Roberta Herman – Director, US national, 52 years.



Residing in the United States, Roberta Herman, a doctor of medicine, is heavily involved in the digitisation of the medical sector, particularly chronic diseases such as diabetes and cancer.

She is currently the Executive Manager of the Massachusetts Insurance Group Commission, and previously worked at Navigant Consulting for more than two years. She was also jointly responsible for the value transformation and healthcare strategy for payer/supplier integrations.

She was a member of the New England Healthcare Institute Board of Directors, working on various aspects, such as: pharmacy, payers, suppliers and technology to advance digital and telehealth solutions.

Thanks to her participation on a number of boards of directors, she has also developed an extensive network of payers.

A doctor of medicine, Roberta Herman holds degrees from Wharton School, University of Pennsylvania, and from McGill University,

Alain Parthoens – Permanent representative of Vesalius Biocapital II, Observer, Belgian national,

59 years old.



Alain Parthoens is co-founder and managing partner of Vesalius Biocapital funds I & II. He launched his first pan-European life science venture capital fund end of 2007 (VBC I, €76M raised) invested in 11 life science companies. In 2011, Vesalius raised its second fund (VBC II) of €78 million, invested in 11 companies at present.

Alain Parthoens has 17 years of experience as a venture capitalist with Vesalius Biocapital as well as ING Bank, where he was the life sciences investment director for southwestern Europe. Since 2001, he has invested in almost 30 early stage life science companies, most of the time in a leading role. As Board member, he has actively participated in the development of several of them. Additionally, Alain Parthoens has many years of international experience working with food and life science companies, such as Nestlé, Kemira and Monsanto, and as an R&D consultant for pharmaceutical companies with PriceWaterhouseCoopers in London.

In 2017, he founded Newton Biocapital, an investment fund that invests in life sciences start-ups in Europe and Japan. Newton Biocapital has offices in Brussels and Tokyo.

Alain holds an MSc in agronomy and specialty biochemistry from the Université Catholique de Louvain, an MSc in finance and computer sciences from Université Libre de Bruxelles and a management degree from the Solvay Business School.

14.2 Conflicts of interest in the administrative bodies and executive management

Pierre Leurent, Romain Marmot, Alexandre Capet and Bpifrance Participations, LBO France Gestion, and Vesalius Biocapital II are direct and/or indirect shareholders of the Company, as detailed in Section 18.2 of the Registration Document.

Eric Elliott and Nicolas Cartier, Viviane Monges, Jan Berger and Roberta Herman are not shareholders, however they hold securities giving access to the Company's share capital (see Section 21.1.4 of the Registration Document).

Related-party agreements are described in Sections 16.2 and 19.2 of the Registration Document.

To the Company's knowledge, there are no current or potential conflicts of interest between duties carried out for the Group and the private interests and/or other duties of the members of the Company's Management and Board of Directors, as set out in Section 14.1 above.

The Board of Directors has adopted rules of procedure of which an article on Directors' "duty of loyalty" stipulates that any members of the Board of Directors who are in such a situation must fully and immediately inform the Board of Directors of any real or potential conflict of interest that they may have in the context of their duties as members of the Board of Directors, to determine whether they should refrain from voting on the resolutions in question, or must not attend the relevant Board meeting, or, in extreme cases, resign from their positions.

In the context of their investment in the Company, CapDecisif and the funds managed by CapDecisif Management, CM-CIC Innovation, Sham Innovation Sante, Bpifrance Participations, Services Innovants Sante et Autonomie (SISA), and Vesalius Biocapital II, together, the "**Investors**") entered into a shareholders agreement dated 14 May 2018 (the "**Agreement**") with Pierre Leurent, Romain Marmot, Etienne Vial, Alexandre Capet and Matthieu Plessis, pursuant to which:

- each of the parties to the Agreement undertakes, with effect from the Company's initial public offering completion date and for a term ending following the General Meeting of Shareholders convened to vote on the financial statements for the year ending 31 December 2020, and within the limits of their respective powers as shareholder and/or member of the Board of Directors, to present, vote and ensure to be voted within all the Company's corporate bodies in favour of all decisions necessary for CM-CIC Innovation, Bpifrance Participations and LBO France (in its capacity as management company of SISA) to retain their position as director and Vesalius Biocapital II his position as observer within the Board of Directors, for as long as the Investor in question continues to hold at least a certain percentage of the number of shares in the Company held by such Investor as of the date of completion of the Company's initial public offering, it being stipulated that each member appointed in this manner must then resign should the Investor in question cease to hold shares in the Company;
- each of the parties to the Agreement must notify the other parties before requesting any exemption from their lock-up undertaking with Bryan, Garnier & Co and Oddo BHF SCA, so that each of the other Parties may, where applicable, decide to concurrently submit a request for dispensation to Bryan, Garnier & Co and to Oddo BHF SCA, on a *pari passu* basis; and
- the parties to the Agreement reiterate their intention not to sell any shares which, by creating a market disruption, would have a material adverse effect on the Voluntis share price and, in order to avoid such effects, to favor, for example, the sale of off-market blocks or to limit the amount of such sales to around 20% of the shares sold on the market on the same day.

It is not the purpose of this Agreement or the intention of the parties to act in concert.

To the Company's knowledge, there is no other pact, arrangement, or agreement of any kind with shareholders, customers, suppliers, or others under which any of the members of the Company's Management or Board of Directors has been named.

Furthermore, as part of the Company's initial public offering, its shareholders representing 99.57% of its share capital have entered into a lock-up undertaking covering 100% of the shares they held on the day of the initial public offering until the end of a period of 365 days following the settlement-delivery date of the Company's shares on the Euronext Paris regulated market, subject to certain standard exceptions.

¹ It being specified that he resigned from his term of office as director, effective 25 October 2018.

To the Company's knowledge, there is, as of the date of this Registration Document, no restriction accepted by persons covered in Section 14.1 above regarding the sale, within a certain time interval, of their holding in the Company's share capital other than the Agreement.

15. COMPENSATION AND BENEFITS

15.1 Compensation of corporate officers

The information in this chapter is based on the Corporate Governance Code as published in September 2016 by MiddleNext. The tables in Appendix 2 to the AMF Position-Recommendation No. 2014-14 are presented below.

The Combined General Meeting of the Company on 11 April 2018 has approved the change in the Company's administrative and management mode by adopting a structure with a board of directors. At their meeting held on 11 April 2018, the Board of Directors opted to separate the positions of Chairman of the Board and Chief Executive Officer.

Readers are invited to consult the details provided in the tables below.

Table No. 1: Summary table of compensation and warrants, founders' stock options, options and bonus shares allocated to each corporate officer

	FY 2017	FY 2018
Pierre Leurent – Chief Executive Officer ⁽¹⁾		
Compensation owed for the financial year ⁽²⁾	€224,088	€318,370
Valuation of multi-year variable compensation allocated during the year	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	Non applicable	€139,403
Valuation of free shares allocated for the financial year	Non applicable	Non applicable
Total	€224,088	€457,772

⁽¹⁾ Beginning on 11 April 2018, Pierre Leurent was appointed Chief Executive Officer of the Company in its current form as a French société anonyme with a board of directors. He previously served as Chairman of the Company's Management Board under the form of a public limited company with a management board and a supervisory board.

⁽²⁾ Including benefits in kind (see Table No. 2 "Summary table of compensation of each corporate officer" below).

	FY 2017	FY 2018
Romain Marmot – Deputy Chief Executive Officer⁽¹⁾		
Compensation owed for the financial year ⁽²⁾	€186,777	€197,751
Valuation of multi-year variable compensation allocated during the year	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	Non applicable	€76,625
Valuation of free shares allocated for the financial year	Non applicable	Non applicable
Total	€186,777	€274,377

⁽¹⁾ Beginning on 11 April 2018, Romain Marmot was appointed Deputy Chief Executive Officer of the Company in its current form as a French société anonyme with a board of directors. He previously served as a member of the Management Board and as CEO of the Company, under the form of a public limited company with a management board and a supervisory board.

⁽²⁾ Including benefits in kind (see Table No. 2 "Summary table of compensation of each corporate officer" below).

	FY 2017	FY 2018
Alexandre Capet - Deputy Chief Executive Officer ⁽¹⁾		
Compensation owed for the financial year ⁽²⁾	€160,000	€183,760
Valuation of multi-year variable compensation allocated during the year	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	€0	€0
Valuation of free shares allocated for the financial year	Non applicable	€134,680
Total	€160,000	€318,440

⁽¹⁾ Beginning on 11 April 2018, Alexandre Capet was appointed Deputy Chief Executive Officer of the Company in its current form as a French *société anonyme* with a board of directors. He previously served as a member of the Company's Management Board, under the form of a public limited company with a management board and a supervisory board.

⁽²⁾ Including benefits in kind (see Table No. 2 "Summary table of compensation of each corporate officer" below).

	FY 2017	FY 2018
Eric Elliott – Chairman of the Board of Directors (1)		
compensation owed for the financial year	€64,101	€52,706
Valuation of multi-year variable compensation allocated during the year	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	€27,736	Non applicable
Valuation of free shares allocated for the financial year	Non applicable	Non applicable
Total	€91,837	€52,706

⁽¹⁾ Beginning on 11 April 2018, Eric Elliott was appointed Chairman of the Board of Directors of the Company in its current form as a French *société anonyme* with a board of directors. He previously served as Chairman of the Company's Supervisory Board under the form of a public limited company with a management board and a supervisory board.

Table No 2: Summary table of compensation of each corporate officer

The following tables show the compensation owed to corporate officers for the financial years ended 31 December 2017 and 2018, and the compensation paid to those same individuals during the same financial years.

	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Pierre Leurent – Chief Executive Officer ⁽³⁾				
Fixed compensation ⁽⁴⁾	€156,499	€156,499	€179,199	€179,199
Variable annual compensation ⁽⁵⁾	€18,332	€35,765	€20,169	€18,183
Multi-year variable compensation	Non applicable	Non applicable	Non applicable	Non applicable
Exceptional compensation ⁽⁶⁾	€8,224	€15,000	€35,137	€43,306
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Benefits in kind ⁽⁷⁾	€41,033	€37,581	€83,865	€83,865
Total	€224,088	€244,845	€318,370	€324,554

⁽¹⁾ Compensation owed to the corporate officer during the financial year of which the amount is not likely to change regardless of payment date. Amounts owed in foreign currency are converted at the average rate of the relevant period.

⁽²⁾ Compensation paid to the corporate officer during the financial year. Amounts paid in foreign currency are converted at the average rate of the payment period.

⁽³⁾ See ⁽¹⁾ of Table 1 above.

⁽⁴⁾ Compensation owed for his chairmanship of the Management Board for the period prior to 15 August 2017, then, as from that date, for an employment contract with Voluntis, Inc. The change between 2017 and 2018 is mainly due to the application over the full year of the modified remuneration in August 2017 as part of its relocation.

⁽⁵⁾ Pierre Leurent receives annual variable compensation based on the attainment of qualitative and quantitative objectives set at the beginning of the year. In 2017, these objectives were mainly linked to the Company's revenue, the level of patient engagement, the signing of new contracts and the implementation of certain public affairs initiatives and, in 2018, in addition to qualitative and quantitative targets similar to those set for 2017, the revenue and EBITDA achieved by the Group. Variable compensation in respect of the 2018 financial year was capped at USD 112,800.

Pierre Leurent may also benefit, in respect of the 2019 financial year, from annual variable compensation based on the attainment of Group revenue and EBITDA targets, its organisation and the implementation of certain initiatives to enhance the value and structure of its business activities. This variable compensation will be capped for each target and cannot exceed a total amount of USD 139,400.

⁽⁶⁾ Pierre Leurent received a one-off bonus relating, (i) in respect of the 2017 financial year, to the completion of business development activities, and (ii) in respect of the 2018 financial year, to the success of the initial public offering under predetermined conditions.

As at the date of this Registration Document, no decision has been taken regarding the allocation of any bonus for the 2019 financial year.

⁽⁷⁾ The Company pays for Pierre Leurent's housing and travel costs, due to his relocation to the United States, at the Company's request, as well as unemployment insurance.

	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Romain Marmot – Deputy Chief Executive Officer⁽³⁾				
Fixed compensation ⁽⁴⁾	€144,288	€144,288	€146,047	€146,047
Variable annual compensation ⁽⁵⁾	€22,130	€19,917	€13,616	€21,961
Multi-year variable compensation	€0	€0	€0	€0
Exceptional compensation ⁽⁶⁾	€4,426	€8,852	€21,961	€26,353
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Benefits in kind ⁽⁸⁾	€15,934	€15,934	€16,128	€16,128
Total	€186,777	€188,990	€197,751	€210,488

⁽¹⁾ Compensation owed to the corporate officer during the financial year of which the amount is not likely to change regardless of payment date. Amounts owed in foreign currency are converted at the average rate of the relevant period.

⁽²⁾ Compensation paid to the corporate officer during the financial year. Amounts paid in foreign currency are converted at the average rate of the payment period.

⁽³⁾ See ⁽¹⁾ of Table 1 above.

⁽⁴⁾ Compensation owed under the employment contract with Voluntas, Inc. as Chief Operating Officer.

⁽⁵⁾ Romain Marmot receives annual variable compensation based on the attainment of qualitative and quantitative objectives set at the beginning of the year. In respect of the 2017 financial year, these targets mainly related to the level of patient engagement and the structuring of operations in the United States, including the achievement of hiring targets and, for the 2018 financial year, in addition to qualitative and quantitative targets comparable in nature to those set for the 2017 financial year, to the Group's revenue and EBITDA levels. Variable compensation in respect of these two financial years was capped at USD 28,000 in 2017 and USD 57,000 in 2018.

Romain Marmot may also benefit, in respect of the 2019 financial year, from annual variable compensation paid on the basis of the attainment of qualitative and quantitative objectives similar to those set for the 2018 financial year, in particular the Group's revenue and EBITDA, and qualitative objectives relating to strengthening the Group's organisation and enhancing operating processes. This compensation is capped at USD 85,200.

⁽⁶⁾ Romain Marmot received a bonus relating, (i) in respect of the 2017 financial year, to the coordination of the Group's activities in the field of oncology and (ii) in respect of the 2018 financial year, to the success of the initial public offering under predetermined conditions.

As at the date of this Registration Document, no decision has been taken regarding the allocation of any bonus for the 2019 financial year.

⁽⁷⁾ Romain Marmot's extraordinary bonus is paid in USD. The difference between the monies owed and those actually paid to the latter comes from the change in the USD/EUR exchange rate between the date of the decision establishing the compensation and the date on which it is paid.

⁽⁸⁾ Romain Marmot's housing and travel costs are paid by the Company due to his relocation to the United States, at the Company's request.

	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Alexandre Capet - Deputy Chief Executive Officer ⁽³⁾				
Fixed compensation ⁽⁴⁾	€140,000	€140,000	€142,800	€142,800
Variable annual compensation ⁽⁵⁾	€14,000	€27,254	€15,960	€14,717
Multi-year variable compensation	€0	€0	€0	€0
Exceptional compensation ⁽⁶⁾	€6,000	€10,000	€25,000	€31,000
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Benefits in kind	€0	€0	€0	€0
Total	€160,000	€177,254	€183,760	€188,517

⁽¹⁾ Compensation owed to the corporate officer during the financial year of which the amount is not likely to change regardless of payment date.

⁽²⁾ Compensation paid to the corporate officer during the financial year.

⁽³⁾ See ⁽¹⁾ of Table 1 above.

⁽⁴⁾ Compensation owed under the employment contract with the Company as Chief Strategy & Marketing Officer.

⁽⁵⁾ Alexandre Capet receives annual variable compensation based on the attainment of qualitative and quantitative objectives set at the beginning of the year. For the 2017 financial year, these targets mainly related to the level of patient engagement, the development of the Group's product portfolio, the Group's communication and industrialisation processes and, for the 2018 financial year, in addition to qualitative and quantitative targets similar to those set for the 2017 financial year, to the revenue and EBITDA achieved by the Group in 2018. Variable compensation in respect of these two financial years was capped at USD 28,000 in 2017 and USD 47,700 in 2018.

Alexandre Capet may also benefit, in respect of the 2019 financial year, from annual variable compensation paid based on the attainment of qualitative and quantitative targets similar to those set for 2018, and to targets relating to the development of the Group's product portfolio, organisation and the management of alliances with partners, as well as the revenue and EBITDA achieved by the Company. This compensation is capped at USD 76,500.

⁽⁶⁾ Alexandre Capet received a one-off bonus relating, (i) in respect of the 2017 financial year, to the completion of business development activities, and (ii) in respect of the 2018 financial year, to the success of the initial public offering under predetermined conditions. It has not been previously provided that Alexandre Capet may be granted exceptional bonuses in respect of the 2019 financial year.

As at the date of this Registration Document, no decision has been taken regarding the allocation of any bonus for the 2019 financial year.

	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Eric Elliott – Chairman of the Board of Directors (3)				
Fixed compensation	€53,112	€53,112	€52,706	€52,706
Annual variable compensation	Non applicable	Non applicable	Non applicable	Non applicable
Multi-year variable compensation	Non applicable	Non applicable	Non applicable	Non applicable
Exceptional compensation ⁽⁴⁾	€10,989	€10,989	Non applicable	Non applicable
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Benefits in kind	Non applicable	Non applicable	Non applicable	Non applicable
Total	€64,101	€64,101	€52,706	€52,706

⁽¹⁾ Compensation owed to the corporate officer during the financial year of which the amount is not likely to change regardless of payment date.

⁽²⁾ Compensation paid to the corporate officer during the financial year.

⁽³⁾ See ⁽¹⁾ of Table 1 above.

⁽⁴⁾ In respect of the 2017 financial year, Eric Elliott received additional compensation due to his exceptional participation in the Company's strategic seminar.

Table No.3: Attendance fees and other compensation received by corporate officers

Non-executive directors	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Nicolas Cartier ⁽³⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	65.407		Non applicable	
CM-CIC Innovation (represented by Emilie Lidome) ⁽⁴⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Bpifrance Participations (represented by Jean Bertin then, as of 10 January 2019, by Laurent Higueret) ⁽⁵⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable

Non-executive directors	FY 2017		FY 2018	
	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾	Amounts due ⁽¹⁾	Amounts paid ⁽²⁾
Vesalius Biocapital II Partners sarl (represented by Alain Parthoens) ⁽⁶⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Turenne Capital Partenaires SA (represented by Benoît Pastour) ⁽⁷⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
LBO France Gestion (represented by Franck Noiret) ⁽⁵⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	Non applicable
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Viviane Monges ⁽⁸⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	€115,022
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	Non applicable		€0	
Jan Berger ⁽⁹⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	€89,467
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	Non applicable		€0	
Roberta Herman ⁽⁹⁾				
Attendance fees	Non applicable	Non applicable	Non applicable	€89,467
Other compensation	Non applicable	Non applicable	Non applicable	Non applicable
Valuation of warrants, founders' stock options and Options allocated during the year	Non applicable		€0	

⁽¹⁾ Compensation owed to the corporate officer during the financial year of which the amount is not likely to change regardless of payment date.

⁽²⁾ Compensation paid to the corporate officer during the financial year.

⁽³⁾ Over the period in question, Nicolas Cartier was Vice-President of the Supervisory Board of the Company in its form as a French *société anonyme* with a management board and a supervisory board. Beginning on 11 April 2018, he was appointed director of the Company in its current form as a French *société anonyme* with a board of directors.

⁽⁴⁾ CM-CIC Innovation resigned from its term of office as director on 25 October 2018, with immediate effect.

- (5) Over the period in question, each of these individuals was a member of the Company's Supervisory Board in its form as a French *société anonyme* with a management board and a supervisory board. Beginning on 11 April 2018, each of them was appointed director of the Company in its current form as a French *société anonyme* with a board of directors.
- (6) Over the period in question, Vesalius Biocapital II Partners was a member of the Supervisory Board of the Company in its form as a French *société anonyme* with a management board and a supervisory board. Beginning on 11 April 2018, it was appointed observer of the Company in its current form as a French *société anonyme* with a board of directors.
- (7) Over the period in question and until 11 April 2018, Turenne Capital Partenaires was a member of the Supervisory Board of the Company in its form as a French *société anonyme* with a management board and a supervisory board.
- (8) Over the period in question since his appointment at the General Shareholders' Meeting held on 11 April 2018, 2018 attendance fees include an exception component of €82,800, having been offset against the subscription price of the warrants allocated to Viviane Monges. Given the subscription price of the warrants at their fair value at the date of issue under the Black & Scholes method, this allocation did not result in any expense being recognised in the Group's consolidated financial statements in addition to the attendance fees. This increase in the amount of attendance fees is intended to put the Company in a position to be able to appoint directors who are active in the US market. It is indeed common practice in the United States to put in place a directors' compensation policy comprised not only of attendance fees but also of share purchase options (equity component).
- (9) Over the period in question since their appointment and cooptation on 25 October 2018, 2018 attendance fees include an exception component of €82,800, having been offset against the subscription price of the warrants allocated to the two directors concerned. Given the subscription price of the warrants at their fair value at the date of issue under the Black & Scholes method, this allocation did not result in any expense being recognised in the Group's consolidated financial statements in addition to the attendance fees. This increase in the amount of attendance fees is intended to put the Company in a position to be able to appoint directors who are active in the US market. It is indeed common practice in the United States to put in place a directors' compensation policy comprised not only of attendance fees but also of share purchase options (equity component).

Table No. 4: Warrants, founders' stock options or options allocated during the financial year ended 31 December 2018 to each corporate officer by the Company and by any company in the Group

Name of Corporate Officer	Date of allocation	Nature of BSAs (warrants)	Valuation of BSAs by the Black & Scholes method	Number of BSAs allocated during the FY	Maximum number of shares likely to be issued when exercising the BSAs	Exercise price	Expiry date
Pierre Leurent	11 April 2018	Options ₂₀₁₈	139,403	€23,405	23,405	€14	11 April 2028
Romain Marmot	11 April 2018	Options ₂₀₁₈	76,625	€12,865	12,865	€14	11 April 2028

Table No. 5: Warrants and founders' stock options exercised and options exercised during the financial year ended 31 December 2018 by each corporate officer

Non applicable.

Table No. 6: Free shares allocated to each corporate officer by the Company

Bonus shares granted by the General Shareholders' Meeting during the financial year to each corporate officer by the Company (registered list)	Date of allocation	Number of bonus shares allocated during the year	Valuation of shares at fair value at the time of grant	Vesting date	End of lock-in period	Performance conditions
Alexandre Capet	11 April 2018	9,620	€134,680	11 April 2019	11 April 2020	Non applicable

Table No. 7: Free shares made available for each corporate officer

Non applicable.

Table No. 8: Past allocations of warrants, founders' stock options and options allocated

See tables in Sections 21.1.4.1 to 21.1.4.3 of the Registration Document.

Table No 9: Warrants and founders' stock options allocated and options granted during the financial year to the top ten non-executive managers, and warrants and founders' stock options and options exercised during the financial year by the latter

	Total number of options allocated - of shares subscribed or purchased	Weighted average price per share	Options 2018
Number of options granted during the year by the Company to the ten employees who are not corporate officers of the Company, with the highest number of options	5,000	€14	5,000
Number of warrants and/or founders' stock options exercised or options exercised, during the financial year, by the ten employees of the Company, of which the number of warrants and founders' stock options so exercised or options so exercised is the highest	Non applicable	Non applicable	Non applicable

Table No. 10: Past allocations of free shares

See tables in Sections 21.1.4.1 to 21.1.4.3 of the Registration Document.

Table No. 11

The following table provides details about the conditions of compensation and other benefits for corporate officers:

Corporate Officers	Employment contract		Supplemental pension scheme		Allowance or benefits owed or likely to be owed due to a termination or change of position		Allowance related to a non-competition clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Pierre Leurent – Chief Executive Officer	X ⁽¹⁾			X	X ⁽²⁾		X ⁽³⁾	
Term of office start date:	11 April 2018							
Term of office end date:	On the expiry date of the directorship, i.e. at the end of the Annual General Meeting approving the financial statements for the year ending 31 December 2020							
Romain Marmot - Deputy Chief Executive Officer	X ⁽⁴⁾			X	X ⁽⁵⁾		X ⁽⁶⁾	
Term of office start date:	11 April 2018							
Term of office end date:	For the term of office of the Chief Executive Officer							
Alexandre Capet - Deputy Chief Executive Officer	X ⁽⁷⁾			X		X	X ⁽⁸⁾	

Corporate Officers	Employment contract		Supplemental pension scheme		Allowance or benefits owed or likely to be owed due to a termination or change of position		Allowance related to a non-competition clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Term of office start date:	11 April 2018							
Term of office end date:	For the term of office of the Chief Executive Officer							
Eric Elliott - Chairman of the Board of Directors		X		X		X		X
Term of office start date:	11 April 2018							
Term of office end date:	On the expiry date of the directorship, i.e. at the end of the Annual General Meeting approving the financial statements for the year ending 31 December 2020							

- (1) Employment contract entered into on 15 August 2017 with Voluntis, Inc. as Chief Executive Officer. The Board of Directors meeting held on 11 April 2018 confirmed that this employment contract would continue.
- (2) In the event of termination of Pierre Leurent's employment contract, his costs to relocate to France will be paid by Voluntis Inc. up to the amount of USD 10,000. Moreover, Pierre Leurent has unemployment insurance (social security for corporate heads and executives).
- (3) Pursuant to his employment contract, Voluntis Inc. could ask Pierre Leurent to respect a non-compete obligation for a period of 12 to 24 months from the date of termination of his employment contract. In consideration for this obligation, Pierre Leurent will receive, after the actual termination of his employment contract and for the duration of his non-compete obligation, a monthly allowance equal to 45% of the compensation (salary, benefits and bonus) that he would have received for the last 12 months of presence in the Company; this compensation shall be paid to him on a bi-monthly basis.
- (4) Employment contract entered into on 4 April 2014 with Voluntis, Inc. as Chief Operating Officer. The Board of Directors meeting held on 11 April 2018 confirmed that this employment contract would continue.
- (5) In the event that Romain Marmot's employment contract is breached because of a transfer or change in control of the Company, or if this latter decides to put an end to his activities in the United States without offering Romain Marmot another position, the costs of relocating Romain Marmot and his family to France will be paid by Voluntis Inc. in the amount of USD7,000 maximum (this assessment may be increased by mutual agreement between the parties).
- (6) Pursuant to his employment contract, in consideration for his non-competition obligation, Romain Marmot will receive, after the actual termination of his employment contract and for a period of 6 months from that date, a monthly allowance equal to his last net monthly salary (including premiums and variable compensation).
- (7) Employment contract entered into on 5 November 2012 with the Company as Chief Strategy & Marketing Officer. The Board of Directors meeting held on 11 April 2018 confirmed that this employment contract would continue.
- (8) Pursuant to his employment contract, in consideration for his non-compete obligation, Alexandre Capet will receive, after the actual termination of his employment contract and for a period of one year from that date, a monthly allowance equal to 60% of the gross monthly average of his compensation (wages and premiums) that he would have received during the last 12 months of his tenure with the Company.

It is specified that, with the exception of the information included in table 2 above concerning variable compensation, the Company has no short or medium term plans to amend the compensation policy for its executives.

15.2 Sums provisioned by the Company for the payment of pensions, retirements, and other benefits to corporate officers

With the exception of provisions for the retirement allowance of Alexandre Capet, in the amount of €12,907 at 31 December 2018, as permitted by law, the Company has not provisioned any sums for the payment of pensions, retirement, or other benefits for corporate officers.

In addition, in accordance with the decision of the Supervisory Board meeting held on 12 June 2015, the Company paid Eric Elliott a hiring bonus of USD 50,000 upon his appointment as Chairman of the Supervisory Board.

15.3 Securities giving access to the Company's share capital allocated to or subscribed by corporate officers

A detailed description of the terms of each of the plans mentioned above appears in Section 21.1.4 of the Registration Document. The figures shown are for the number of shares that can be subscribed per exercise of each of the rights or transferable securities giving access to the share capital.

15.4 Principles and criteria for determining, distributing and assigning the fixed, variable and exceptional components composing the total compensation and benefits of any kind attributable to the Chairman of the Board of Directors, Chief Executive Officer and Deputy Chief Executive Officers

Pursuant to Article L. 225-37-2 of the French Commercial Code, the Board of Directors submits for the approval of the General Shareholders' Meeting convened to vote on the financial statements for the year ended 31 December 2018 the principles and criteria applicable for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits of all kinds attributable to the Chairman of the Board of Directors, the Chief Executive Officer and Deputy Chief Executive Officers in respect of their duties during the 2019 financial year and which form the compensation policy that applies to them. These principles and criteria, adopted by the Board of Directors on the recommendation of the Appointments and Compensation Committee, are presented below:

15.4.1 Chairman of the Board of Directors

The Chairman of the Board of Directors receives attendance fees, the amount of which is decided on by the Board of Directors (within the limit of the amount approved at the general meeting) and the criteria set by the Board of Directors, based on their attendance and the time they devote to their duties, including, where applicable, on the committee(s) set up by the Board of Directors.

In respect of his term of office as Chairman of the Board of Directors, Eric Elliott receives gross annual compensation of USD 60,000, payable in four instalments of USD 15,000 on 1 February, 1 May, 1 August and 1 November each year, and is entitled to a reimbursement of his hospitality and travel expenses, upon presentation of receipts.

He may also be offered the option to subscribe, in return for payment, to share warrants.

Furthermore, in his capacity as a member of the Board of Directors, he may also receive compensation in respect of specific assignments that may be entrusted to him by the Board of Directors and which

would be the subject of regulated agreements submitted for the shareholders' approval.

15.4.2 [Pierre Leurent, Chief Executive Officer](#)

It should be noted that Pierre Leurent does not receive any compensation in respect of his term of office as Chief Executive Officer. All of his compensation is paid to him under his employment contract with Voluntis Inc. as Chief Executive Officer and the continuation of which was approved by the Board of Directors at the meeting held on 11 April 2018.

Items of compensation	Principles	Calculation criteria
Fixed compensation		The gross annual amount of this fixed compensation was set at USD 204,000 for the 2019 financial year.
Variable compensation	Variable compensation of up to 40% of the fixed compensation. In the event that targets are exceeded, such compensation may reach up to 56% of the fixed annual compensation.	This variable compensation is based on performance targets linked to revenue, EBITDA and the attainment of commercial objectives. The targets are defined by the Board of Directors, reviewed by the Compensation Committee and then approved by the Board of Directors. Whether or not the targets have been achieved is assessed by the Compensation Committee and the Board of Directors. For the sake of confidentiality, these targets are not publicly disclosed.
Exceptional compensation	The Chief Executive Officer may be granted exceptional compensation.	This exceptional compensation would be intended to compensate a particular performance on one or more initiatives having a major impact on the Company's development, such as acquisitions, mergers or changes of control.
Bonus	The Chief Executive Officer may be granted bonuses in the event of an exceptional event having a significantly positive impact on the Company.	
Benefits in kind	GSC cover	In 2019, the contribution amounted to €20,513.
	Relocation fee	The Company shall cover accommodation and travel costs following a relocation at the Company's request. The amount covered shall not exceed USD 100,000.
Supplemental pension scheme	The Chief Executive Officer does not benefit from a supplementary pension scheme.	

The Chief Executive Officer may be granted stock options or share purchase options and/or bonus shares subject to conditions of presence and performance.

Finally, it is hereby specified that Pierre Leurent does not receive any attendance fees or other compensation in respect of his terms of office at Company subsidiaries, and, does not benefit from long-term multi-year compensation other than, on a case-by-case basis, the allocation of stock options or share purchase options and/or bonus shares, subject to conditions of presence and performance.

15.4.3 [Romain Marmot, Deputy Chief Executive Officer](#)

It should be noted that Romain Marmot does not receive any compensation in respect of his term of office as Deputy Chief Executive Officer. All of his compensation is paid to him under his employment contract with Voluntis Inc. as *Chief Operating Officer*, the continuation of which was approved by the Board of Directors at the meeting held on 11 April 2018.

Items of compensation	Principles	Calculation criteria
Fixed compensation		The gross annual amount of this fixed compensation was set at USD 166,260 for the 2019 financial year.
Variable compensation	Variable compensation of up to 30% of the fixed compensation. In the event that targets are exceeded, such compensation may reach up to 42% of the fixed annual compensation.	This variable compensation is based on performance targets linked to revenue, EBITDA and the attainment of commercial objectives. The targets are defined by the Board of Directors, reviewed by the Compensation Committee and then approved by the Board of Directors. Whether or not the targets have been achieved is assessed by the Compensation Committee and the Board of Directors. For the sake of confidentiality, these targets are not publicly disclosed.
Exceptional compensation	The Deputy Chief Executive Officer may be granted exceptional compensation.	This exceptional compensation would be intended to compensate a particular performance on one or more initiatives having a major impact on the Company's development, such as acquisitions, mergers or changes of control.
Bonus	The Deputy Chief Executive Officer may be granted bonuses in the event of an exceptional event having a significantly positive impact on the Company.	
Benefits in kind	Relocation fee	The Company shall cover accommodation and travel costs following a relocation at the Company's request. The amount covered shall not exceed USD 20,000.
Supplementary pension scheme	The Deputy Chief Executive Officer does not benefit from a supplementary pension scheme.	

The Deputy Chief Executive Officer may be granted stock options or share purchase options and/or bonus shares subject to conditions of presence and performance.

Finally, it is hereby specified that Romain Marmot does not receive any other compensation in respect of his terms of office at Company subsidiaries, and, does not benefit from long-term multi-year compensation other than, on a case-by-case basis, the allocation of stock options or share purchase options and/or bonus shares, subject to conditions of presence and performance.

15.4.4 [Alexandre Capet, Deputy Chief Executive Officer](#)

It should be noted that Alexandre Capet does not receive any compensation in respect of his term of office as Deputy Chief Executive Officer. All of his compensation is paid under the employment contract entered into with the Company as Chief Strategy & Marketing Officer, the continuation of which was approved by the Board of Directors at its meeting held on 11 April 2018.

Items of compensation	Principles	Calculation criteria
Fixed compensation		The gross annual amount of this fixed compensation was set at USD 152,800 for the 2019 financial year.
Variable compensation	Variable compensation of up to 30% of the fixed compensation. In the event that targets are exceeded, such compensation may reach up to 41% of the fixed annual compensation.	This variable compensation is based on performance targets linked to revenue, EBITDA and the attainment of commercial objectives. The targets are defined by the Board of Directors, reviewed by the Compensation Committee and then approved by the Board of Directors. Whether or not the targets have been achieved is assessed by the Compensation Committee and the Board of Directors. For the sake of confidentiality, these targets are not publicly disclosed.
Exceptional compensation	The Deputy Chief Executive Officer may be granted exceptional compensation.	This exceptional compensation would be intended to compensate a particular performance on one or more initiatives having a major impact on the Company's development, such as acquisitions, mergers or changes of control.
Bonus	The Deputy Chief Executive Officer may be granted bonuses in the event of an exceptional event having a significantly positive impact on the Company.	
Benefits in kind		
Supplementary pension scheme	The Deputy Chief Executive Officer does not benefit from a supplementary pension scheme.	

The Deputy Chief Executive Officer may be granted stock options or share purchase options and/or bonus shares subject to conditions of presence and performance.

Finally, it is hereby specified that Alexandre Capet does not receive any other compensation in respect of his terms of office at Company subsidiaries, and, does not benefit from long-term multi-year compensation other than, on a case-by-case basis, the allocation of stock options or share purchase options and/or bonus shares, subject to conditions of presence and performance.

Pursuant to Article L. 225-100 of the French Commercial Code, the amounts arising from the application of the aforementioned principles and criteria shall be submitted to the shareholders for their approval at the General Meeting convened to vote on the financial statements for the year ending 31 December 2019.

15.4.5 [Resolutions submitted to a vote by the shareholders](#)

We hereby propose that you approve the principles and criteria as presented above as well as the related resolutions submitted for your approval, the details of which are set out below:

Eleventh resolution

Approval of the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind attributable to Eric Elliott in respect of his term of office as Chairman of the Board of Directors in 2019

The General Meeting, having considered the reports of the Management Board and the Statutory Auditors,

having read the report prepared pursuant to the provisions of Article L. 225-37-2 of the French Commercial Code,

hereby approves the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind presented in the aforementioned report, and attributable to Eric Elliott for the 2019 financial year in respect of his term of office as Chairman of the Board of Directors.

Twelfth resolution

Approval of the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind attributable to Pierre Leurent in respect of his term of office as Chief Executive Officer in 2019

The General Meeting, having considered the reports of the Management Board and the Statutory Auditors,

having read the report prepared pursuant to the provisions of Article L. 225-37-2 of the French Commercial Code,

hereby approve the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind presented in the aforementioned report and attributable to Pierre Leurent in 2019 in respect of his term of office as Chief Executive Officer.

Thirteenth resolution

Approval of the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind attributable to Romain Marmot in respect of his term of office as Deputy Chief Executive Officer in 2019

The General Meeting, having considered the reports of the Management Board and the Statutory Auditors,

having read the report prepared pursuant to the provisions of Article L. 225-37-2 of the French Commercial Code,

hereby approve the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind presented in the aforementioned report and attributable to Romain Marmot in 2019 in respect of his term of office as Deputy Chief Executive Officer.

Fourteenth resolution

Approval of the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind attributable to Alexandre Capet in respect of his term of office as Deputy Chief Executive Officer in 2019

The General Meeting, having considered the reports of the Management Board and the Statutory Auditors,

having read the report prepared pursuant to the provisions of Article L. 225-37-2 of the French Commercial Code,

hereby approve the principles and criteria for calculating, distributing and allocating the fixed, variable and exceptional items comprising the total compensation and benefits in kind presented in the aforementioned report and attributable to Alexandre Capet in 2019 in respect of his term of office as Deputy Chief Executive Officer.

15.5 Summary report on trading by officers and the persons referred to in Article L. 621-18-2 of the French Financial and Monetary Code in the shares of the Company during the past year.

During the 2018 financial year, the Company received the following trading reports from its executive officers:

Summary report on trading by officers and the persons referred to in Article L. 621-18-2 of the French Financial and Monetary Code in the shares of the Company during the past year.				
Person concerned	Type of transaction	Date of transaction	Number of shares	Unit price
Bpifrance Participations SA	Additions	26 Oct 18	9,000	€6.0000
Bpifrance Participations SA	Additions	26 Oct 18	3,922	€5.9982
Bpifrance Participations SA	Additions	25 Oct 18	21,545	€6.0000
Bpifrance Participations SA	Additions	25 Oct 18	6,023	€6.0525
Bpifrance Participations SA	Additions	24 Oct 18	11,622	€6.8000
Bpifrance Participations SA	Additions	24 Oct 18	1,427	€6.8441
Bpifrance Participations SA	Additions	23 Oct 18	485	€6.7770
Bpifrance Participations SA	Additions	22 Oct 18	200	€6.9000

Summary report on trading by officers and the persons referred to in Article L. 621-18-2 of the French Financial and Monetary Code in the shares of the Company during the past year.

Person concerned	Type of transaction	Date of transaction	Number of shares	Unit price
Bpifrance Participations SA	Additions	19 Oct 18	3,933	€6.9017
Bpifrance Participations SA	Additions	18 Oct 18	2,800	€7.1205
Bpifrance Participations SA	Additions	17 Oct 18	880	€7.1325
Bpifrance Participations SA	Additions	21 Jun 18	447	€12.0000
Bpifrance Participations SA	Additions	20 Jun 18	27,220	€12.0000
Bpifrance Participations SA	Additions	08 Jun 18	300	€12.0000
Bpifrance Participations SA	Additions	08 Jun 18	1,177	€11.9544
Bpifrance Participations SA	Additions	06 Jun 18	410	€11.9000
Bpifrance Participations SA	Additions	05 Jun 18	1,585	€11.4547
Bpifrance Participations SA	Additions	05 Jun 18	2,787	€11.8906
Bpifrance Participations SA	Additions	04 Jun 18	13,344	€11.5418
LBO France Gestion SAS (FCPI Services Innovants Santé)	Conversion of convertible bonds	31 May 18	86,717	€14.0000
LBO France Gestion SAS (FCPI Services Innovants Santé)	Subscription	31 May 18	71,428	€14.0000
CM-CIC Capital Innovation SAS	Conversion of convertible bonds	30 May 18	86,699	€14.0000
CM-CIC Capital Innovation SAS	Subscription	30 May 18	57,142	€14.0000
Bpifrance Participations SA	Conversion of convertible bonds	29 May 18	260,187	€14.0000
Bpifrance Participations SA	Subscription	29 May 18	214,285	€ 14.0000

16. FUNCTIONING OF ADMINISTRATIVE AND MANAGEMENT BODIES

16.1 Company Management

The Company is a French société anonyme with a Board of Directors. This governance structure was adopted by the Combined Shareholders' General Meeting of the Company held on 11 April 2018 (in a shift of governance, from a supervisory board and management board model to a Board of Directors model). At their meeting held on 11 April 2018, the Board of Directors opted to separate the positions of Chairman of the Board and Chief Executive Officer.

The Company's Board of Directors is chaired by Eric Elliot as Chairman of the Board of Directors. The Company's Executive Management includes Pierre Leurent as Chief Executive Officer and Romain Marmot and Alexandre Capet as Deputy Chief Executive Officers. The Chief Executive Officer and Deputy Chief Executive Officers represent the Company to third parties.

16.2 Information on contracts between the Company or its subsidiary and the Company's officers

Employment contract between the Company or its subsidiary, Voluntis, Inc., and the Company's officers

On 15 August 2017, Pierre Leurent entered into an open-ended employment contract governed by US law with Voluntis, Inc. as Chief Executive Officer.

On 4 April 2014, Romain Marmot entered into an open-ended employment contract governed by US law with Voluntis, Inc., as Chief Operating Officer.

On 5 November 2012, Alexandre Capet entered into an open-ended employment contract as Chief Strategy & Marketing Officer. He is currently Chief Operations Officer.

The amounts paid under these contracts during the last financial year are detailed in section 15.2 of the Registration Document.

16.3 Board of Directors and Special Committees - Corporate Governance

16.3.1 [Board of Directors](#)

The composition and information on members of the administrative and management bodies are under the developments described in Chapter 14, "Administrative, Management, Supervisory Bodies, and Executive Management " and Section 21.2, "Memorandum and Articles of Association" in the Registration Document.

Members of the Board may be paid by attendance fees, which are allocated among them according to their attendance record at Board meetings and their participation on special committees.

The rules of procedure, adopted by the Board of Directors at its meeting on 11 April 2018, came into force on 29 May 2018, further to the effective listing of the Company's shares on the regulated market of Euronext in Paris. These rules can only be amended by a two thirds majority of its members.

These rules of procedure stipulate that the following major decisions must have prior approval from the Board of Directors, it being specified that, within the meaning of these rules of procedure, the Group means all companies which Voluntis controls or may control in the future, directly or indirectly, as per the definition of Article L. 233-3 of the French Commercial Code:

- approval and amendment of the annual budget and multi-year budget of any company in the Group;

- the following decisions regarding any company in the Group if those decisions are not individualised in the budget approved by the Board of Directors:
 - to acquire or lease any business goodwill,
 - to create or stop any branch of operations or significant commercial activity,
 - to take, sell, or increase any equity stake in shares or convertible bonds in any other company or grouping,
 - to assign any significant asset (i) whose assignment value (or historic acquisition cost) is greater than one hundred thousand euros or (ii) if the total amount of assignments over a rolling 12-month period exceeds five hundred thousand euros,
 - to acquire any significant asset (i) whose acquisition value would be greater than one hundred thousand euros or (ii) if the total amount of acquisitions made over a rolling 12-month period exceeds five hundred thousand euros,
 - debt and provision of sureties and guarantees in the form of bonds, current account or other deposits, in an amount greater than one hundred thousand euros over a rolling 12-month period,
 - to grant any subsidies or write off any loans to any third parties for an amount greater than one hundred thousand euros,
 - to make loans to employees in an aggregate amount greater than one hundred thousand euros over 12 months,
 - to make loans or write off loans to subsidiaries in an amount greater than one hundred thousand euros per rolling 12-month period, not including the current operation of the intragroup treasury agreement,
 - to acquire, for a per-unit amount of more than fifty thousand euros or for an aggregate amount greater than one hundred thousand euros over 12 months, or assign industrial rights, patents, know-how licences, or brands,
 - appointment/removal and compensation of key executives, the list of which is recorded and amended by the Appointments and Compensation Committee, or hiring/termination of any employee whose yearly fixed/variable compensation is greater than one hundred and fifty thousand euros, for employees located outside the United States, or two hundred thousand euros, for employees located in the United States,
 - to waive all rights against third parties, without compensation, for an amount greater than one hundred thousand euros,
 - to make all decisions to undertake, pursue, or put an end to any litigation between a third-party and a company in the Group that is in the amount of one hundred thousand euros or more,
 - to determine the conditions for the allocation/subscription and vesting, and the recipients, of any shares or transferable securities issued upon delegation of the Extraordinary General Meeting,
 - mergers, demergers, contributions, or similar operations,

- any agreements between one of the Group's companies on the one hand, and the shareholders or related parties on the other,
- change or diversification of activity beyond what is set out in the multi-year budget, and
- transfer of the bulk of the R&D workforce outside France.

In addition, these rules of procedure include the principles of conduct and the obligations of the members of the Company's Board of Directors. All members of the Board inform the Board of any conflicts of interest with which they may be faced. Moreover, these rules of procedure include the rules on distributing and using privileged information in force, and stipulate that its members must abstain from carrying out transactions on the Company's securities when they are in possession of privileged information.

All members of the Board of Directors are duty-bound to report to the Company and the AMF any transactions on Company securities that they perform, directly or indirectly.

The Board of Directors considers that it has four independent members within the meaning of the Corporate Governance Code, as published in September 2016 by MiddleNext (the MiddleNext Code), because Nicolas Cartier, Viviane Monges, Jan Berger and Roberta Herman fulfil all the independence criteria set by the MiddleNext Code (see the table below).

Independence criterion per MiddleNext definition	Nicolas Cartier	Viviane Monges	Jan Berger	Roberta Herman
Has not been, during the past five years, and is not currently an employee or corporate officer of the Company or of a company in its group.	✓	✓	✓	✓
Has not been, during the past two years, and is not currently in a significant business relationship with the Company or its group.	✓	✓	✓	✓
Is not a major shareholder in the Company and does not hold a significant percentage of the voting rights.	✓	✓	✓	✓
Has no close relationship or close family ties with a corporate officer or a major shareholder.	✓	✓	✓	✓
Has not been, in the past six years, a statutory auditor of the Company.	✓	✓	✓	✓

The Company now complies with the applicable regulations and will take care to maintain a certain balance between independent and non-independent directors on the Board of Directors.

Following the cooptation of Roberta Herman as a Company Director to replace CM-CIC Innovation, which resigned, and the appointment of Jan Berger, the Company complies with the provisions of Article L. 225-18-1 of the French Commercial Code regarding gender equality on boards of directors, said Board being made up of three women and five men.

The number of Board meetings reflects the different events in the life of the Company. Thus, the Board of Directors meets more often when the Company's affairs require it and at least four times per year.

As of the date of this Registration Document, the Board of Directors also includes one observer, Vesalius Biocapital II, represented by Alain Parthoens.

Observers are convened to the Board meetings in the same conditions as Board members, and as such they are entitled to advance information about the Board meetings in the same conditions as the Board members. They attend Board meetings with consultative votes only (see Section 21.2.2.1.3 of the Registration Document containing the statutory regulations on observers).

Instituted on 11 April 2018, the Board of Directors met 13 times. The average rate of attendance at meetings over the period was 82%.

16.3.2 Committees

The Company has instituted three special committees within its Board of Directors: an Audit Committee, an Appointments and Compensation Committee and a Strategy Committee.

16.3.2.1 Audit Committee

By a decision from the Board of Directors dated 11 April 2018, the Company established an Audit Committee for an unspecified period. Audit Committee members have set out the operating rules for their committee in the rules of procedure approved by the Board of Directors which will come into force when the Company's shares are listed on the regulated market of Euronext in Paris.

The main terms of the Audit Committee's rules of procedure are described below.

Composition

If possible, the Audit Committee is composed of at least two members appointed, on the recommendation of the Appointments and Compensation Committee, by the members of the Board of Directors, excluding executive corporate officers.

The composition of the Audit Committee may be amended by the Board of Directors and, whatever the case, must be amended if there is a change in the overall composition of the Board.

The members of the Audit Committee are appointed for a period, which cannot exceed their term of office as member of the Board of Directors and can even be revoked by the Board. Their term is renewable without limitation. At least one member of the Committee (preferably its Chair) must be an independent member according to the criteria defined by the MiddleNext Code, and have special financial or accounting skills, with the specification that all members possess at least minimal skills in finance and accounting.

As of the date of this Registration Document, the Audit Committee members are:

- Viviane Monges, Chairman, and
- Bpifrance Participations, represented by Laurent Higuieret.

Viviane Monges an independent member, has special financial and accounting skills.

Responsibilities

The Audit Committee is tasked with:

- monitor the process of preparing financial reporting, including reviewing, prior to their presentation to the Board of Directors, the annual or half-year company and consolidated financial statements and quarterly financial presentations, and ensure that accounting methods used in the preparation of these financial statements and/or presentations are relevant and consistent. The Audit Committee will focus on major transactions during which any conflict of interest could have arisen and examine any conflicts of interest that may affect a member of the Board of Directors, and will propose measures to remedy them; generally speaking, the Audit Committee watches over the quality of the financial information supplied to shareholders;
- monitoring the effectiveness of the internal control, internal audit and risk management systems; and to monitor financial and accounting reporting: as such, the Audit Committee must be informed by the Board of Directors, Chief Executive Officer, Deputy Chief Executive Officers and/or Statutory Auditors of the Company:
 - of any event exposing the Group to a material risk,
 - of the Group's main environmental, social, and societal risks, and
 - of any material defect or weakness in internal control and any substantial fraud;
- ensure monitoring the Statutory Auditors' legal control of the annual and consolidated financial statements;
- issuing a recommendation on the Statutory Auditors proposed for appointment by the General Meeting and reviewing the terms of their compensation;
- monitoring the independence of Statutory Auditors;
- reviewing the terms of use on derivatives;
- periodically reviewing the status of major litigation;
- generally, providing any advice and making any appropriate recommendations in the above areas.

The Audit Committee reviews the annual corporate governance report.

The Audit Committee ensures that there is an anti-fraud and anti-corruption system.

It must regularly account for the performance of its duties and immediately report any difficulty encountered.

Operating procedures

The Audit Committee meets at least twice per year, according to a schedule set by its chairman, to review the annual, half-yearly, and, as applicable, quarterly financial statements (in each case, consolidated, as applicable), following an agenda drawn up by its Chairman and sent to Audit Committee members at least five days before the meeting date. It also meets at the request of its chairman, two of its members, or the Chairman of the Board of Directors of the Company.

The Audit Committee may consult with any executive or director of the Company and carry out any internal or external audit on any topic that it deems to be within its purview. The Chairman of the Audit Committee notifies the Board of Directors of such in advance. In particular, the Audit Committee has the option of consulting with individuals who are involved in the preparation or inspection of the financial statements, the Chief Operating Officer, the Chief Financial Officer, and the principal managers in the Finance Department.

The Audit Committee consults with the Statutory Auditors. It can consult with them without any Company representative.

Reports

The Chairman of the Audit Committee ensures that the Audit Committee's accountability reports to the Board of Directors allow this latter to be fully informed, thereby facilitating its deliberations.

The annual report includes a briefing on the Audit Committee's activity during the preceding financial year.

If, in the course of its work, the Audit Committee detects a significant risk that it deems not to be adequately handled, the Chairman alerts the Chairman of the Board without delay.

The Audit Committee met 3 times in 2018, with 100% attendance. In particular, it:

- reviewed the 2017 financial statements;
- reviewed the interim financial statements at 30 June 2018; and
- directed work to prepare the 2018 financial statements, for review in 2019.

16.3.2.2 Appointments and Compensation Committee

By a decision of the Board of Directors on 11 April 2018, an Appointments and Compensation Committee was established for an unspecified period. The members of this Committee have set out the operating rules of their Committee in rules of procedure approved by the Board of Directors on the same date and which will come into force from the effective listing of the Company's shares on the regulated market of Euronext in Paris.

The primary terms of the Appointments and Compensation Committee's rules of procedure are described below.

Composition

The Appointments and Compensation Committee is composed of at least two members chosen by the Board of Directors from among its members.

The composition of the Appointments and Compensation Committee may be amended by the Board of Directors and, whatever the case, must be amended if there is a change in the overall composition of the Board.

The Appointments and Compensation Committee members are appointed for a period, which cannot exceed their term of office as member of the Board of Directors and can even be revoked by the Board. Their term is renewable without limitation. The Committee is preferably chaired by an independent member, as per the definition in the MiddleNext Code.

As of the date of this Registration Document, the members of the Appointments and Compensation Committee are:

- Nicolas Cartier, Chairman,

- LBO France represented by Franck Noiret, and
- Roberta Herman.

Responsibilities

The Appointments and Compensation Committee is tasked with:

- with regard to nomination:
 - presenting the Board of Directors with recommendations on the composition of the Board of Directors and its Committees, guided by the interest of the Company's shareholders. The committee must strive to reflect a diversity of experiences and points of view, while ensuring a high level of skills, internal and external credibility and stability of the Company's corporate bodies,
 - each year, giving the Board of Directors the list of its members who may be considered "independent members" with regard to the criteria set out by the MiddleNext code,
 - creating a succession plan for the Company's officers, and assisting the Board of Directors in choosing and evaluating the members of the Board of Directors,
 - preparing the list of individuals they recommend for membership in general management or the Board of Directors, by taking the following criteria into account: (i) the desirable balance in the composition of the board of directors in view of the composition and evolution of the Company's shareholding, (ii) the desirable number of independent members, (iii) the proportion of men and women required by the regulation in force, (iv) the opportunity for renewal of terms of office and (v) the integrity, skill, experience and independence of each candidate;
 - preparing the list of Board members whose nomination they recommend for membership in a Committee; and
 - to prepare the list of key executives each year ((i.e. the Chief Executive Officer, Deputy Chief Executive Officers, Chief Financial Officer, Chief Medical Officer, and Chief US Operating Officer, on the date of this Registration Document);
- with regard to compensation:
 - reviewing the primary objectives proposed by management with regard to the compensation of the Company's non-executive managers, and, where appropriate, its subsidiaries, including free share plans and stock subscription or purchase options,
 - reviewing the compensation of non-executive managers of the Company and, where appropriate, of its subsidiaries, including free share plans and stock subscription or purchase options, pension and provident schemes, and benefits in kind,
 - reviewing the primary objectives of any free share plan under consideration for the benefit of the Company's employees and, where appropriate, its subsidiaries,
 - making recommendations and proposals to the Board of Directors regarding:
 - compensation pension and provident schemes, benefits in kind, and other financial entitlements (payment of exceptional bonus), including in the event of closure (compensation related to joining or leaving office, compensatory allowances for a non-compete clause, etc.) for corporate officers of the Company and, where

appropriate, its subsidiaries. The committee proposes compensation amounts and structures and, specifically, rules for setting the variable portion, factoring in the Company's and, where appropriate, its subsidiaries' strategy, objectives, and results, as well as market practices; and

- free share plans, stock subscription or purchase plans, and any other similar profit-sharing mechanisms, particularly individual awards to corporate officers who are eligible for this type of mechanism,
- to ensure that the compensation policy for Executive Corporate Officer and for other senior executives non-directors is consistent,
- to watch over the Company's respect of its transparency requirements with regard to compensation. For the preparation of its proposals and projects, the Appointments and Compensation Committee takes into account market practices in corporate governance;
- reviewing the total amount of attendance fees and the system of their distribution among directors, taking account of the directors' attendance rates and the time they devote to their duties, including, as applicable, on the Committees set up by the Board of Directors, as well as the conditions for reimbursing any costs incurred by Board members,
- preparing and presenting any reports required by the Board of Director's rules of procedure, and
- preparing any other recommendation that the Board of Directors might request of it with regard to compensation.

Generally, the Appointments and Compensation Committee provides any advice and makes any appropriate recommendations in the above areas.

Operating procedures

The Appointments and Compensation Committee meets at least once a year, according to a schedule set by its Chairman, following an agenda drawn up by this latter and sent to Committee members at least five calendar days before the meeting date, except in emergencies as approved unanimously by its members. It also meets whenever it deems necessary, at the request of its chair, two of its members, the Chairman of the Board of Directors, or the Chief Executive Officer.

If the Chairman of the Company's Board of Directors is not a member of the Committee, he or she may be invited to attend the Committee meetings. The Committee invites him/her to present proposals. He or she has no voting rights and does not participate in deliberations regarding his/her own situation.

The Committee may ask the Chairman of the Board of Directors to request the assistance of any management executive in the Company whose skills could facilitate the handling of an item on the agenda. The Committee Chairman or the session chair points out the confidentiality obligation incumbent on any individual participating in the discussions.

The Committee may ask to consult with outside service providers; such services must be approved by the Board of Directors in advance.

Reports

The Chairman of the Appointments and Compensation Committee ensures that the Committee's accountability reports to the Board of Directors allow this latter to be fully informed, thereby facilitating its deliberations.

The annual report includes a briefing on the Committee's activity during the preceding financial year.

The Appointments and Compensation Committee reviews the Company's draft report on executive compensation.

The Appointments and Compensation Committee met 9 times in 2018, with 100% attendance. In particular, it:

- reviewed the compensation of members of the management team (setting variable compensation for 2017, deciding on principles of compensation for 2018);
- reviewed proposals for new stock option (OSA), free share (AGA) and warrant (BSA) allocations to corporate officers, employees and directors;
- reviewed files on proposed directorship candidates with a view to their cooptation or appointment;
- reviewed a compensation scheme for independent directors and proposed it to the Board of Directors;
- reviewed management's proposed organisational changes to Executive Management and approved the creation of new management posts within the US team.

16.3.2.3 Strategy Committee

At the meeting of the Board of Directors on 15 April 2019, the Company decided to establish a Strategy Committee for an unspecified period. Committee members set out rules on how their committee would operate in a set of rules of procedure approved by the Board of Directors the same day.

The main terms of the Strategy Committee's rules of procedure are described below.

Composition

The Strategy Committee is composed of at least two members chosen by the Board of Directors from among its members. These members are selected for their management expertise and experience.

The composition of the Strategy Committee may be amended by the Board of Directors and, whatever the case, must be amended if there is a change in the overall composition of the Board.

The members of the Strategy Committee are appointed for a period that cannot exceed their term of office as a member of the Board of Directors and can even be revoked by the Board. Their term is renewable without limitation.

On the date of this Registration Document, the following people sit on the Strategy Committee:

- Jan Berger, Chairman of the Committee;
- Eric Elliott; and

- LBO France Gestion represented by Franck Noiret.

Their management expertise and experience come from the different employee and management positions they have previously held.

Responsibilities

The Strategy Committee is tasked with reviewing the strategy proposed by Executive Management, draft contracts with a material organisational impact and monitoring issues relating to the Company's policy acquisitions and financing policy.

The Strategy Committee must be consulted on any transfers, acquisitions or disposals, asset contributions, mergers or demergers planned by the Company or by a Group company, whenever the transaction in question involves amounts in excess of corporate or transaction value thresholds and, more generally speaking, as soon as there is a requirement for the operation in question to be approved by the Board of Directors, in accordance with its rules of procedure.

Operating procedures

The Strategy Committee meets as often as is necessary and at least three times a year.

16.4 Corporate Governance

The Company has named the MiddleNext Code as a reference which it intends to turn to once its shares are listed for trading on the regulated market of Euronext in Paris. The code is available on the MiddleNext website(www.middlenext.com).

The Company's aim is to comply with all recommendations in the MiddleNext Code.

The table below shows the Company's position with respect to all recommendations laid down by the MiddleNext code as of the date of this Registration Document.

Recommendations of the MiddleNext Code	Adopted	To be adopted	Under review
Supervisory power			
R 1: Code of ethics for Board members	X		
R 2: Conflicts of interest	X		
R 3: Board composition - Presence of independent members	X		
R 4: Information to Board members	X		
R 5: Organisation of Board and Committee meetings	X		
R 6: Establishment of Committees	X		
R 7: Establishment of rules of procedure for the Board	X ⁽¹⁾		
R 8: Choice of each Board member	X		
R 9: Term of office for Board members			X ⁽¹⁾
R 10: Compensation of Board members	X		
R 11: Establishment of an assessment of the Board's work		X ⁽²⁾	
R 12: Relations with shareholders	X		
Executive power			

Recommendations of the MiddleNext Code	Adopted	To be adopted	Under review
R 13: Definition and transparency of the compensation of executive corporate officers	X		
R 14: Succession planning for executives	X		
R 15: Concurrent employment contract and corporate office	X ⁽³⁾		
R 16: Severance pay	X		
R 17: Supplemental pension schemes	X		
R 18: Stock options and free share allocations		X ⁽⁴⁾	
R 19: Review of focus issues	X		

(1) Directors' reappointments cannot be staggered straight away insofar as current directors were all appointed, or coopted, in 2018. Their terms of office will end at the General Meeting called to approve the 2020 financial statements. An Extraordinary General Meeting may then decide to renew some offices for a shorter term, on an exceptional basis, in order to stagger the terms.

(2) The Company intends to set up an assessment of the Board of Director's work during 2019.

(3) In view of the Company's size, its drive to attract and retain highly experienced personnel, and¹ the specific expertise of each member of general management, the Board of Directors has authorised the executive corporate officers to hold an employment contract and a corporate office concurrently.

(4) The exercise of warrants or founders' stock options allocated to some of the Company's executive corporate officers prior to the listing of the Company's shares on the regulated market of Euronext in Paris is not subject to performance conditions. However, the Company does want to ensure that the exercise of dilutive instruments that will be issued to its executive corporate officers in the future is subject to performance conditions.

16.5 Internal control and risk management procedures set up by the Company

16.5.1 [Definition, objectives and limits of internal control](#)

Internal control is a specific system which aims to ensure:

- compliance with laws and regulations;
- the application of instructions and guidelines set out by the Board of Directors;
- the smooth operation of the Company's internal procedures, particularly those that help to safeguard its assets;
- the reliability of financial information; and
- generally speaking, anything that helps control the Group's activities, the efficacy of its operations and the efficient use of its resources.

One of the objectives of internal control and risk identification procedures is to prevent and control risks of error and fraud, in particular, in accounting and finance. Over the course of the financial year, the Group continued to implement internal control procedures intended to guarantee the relevance and reliability of the information used internally, and disseminated in Company operations.

¹ The protections attached to receiving an employment contract (specifically, dismissal procedure and unemployment benefits) are an important consideration for executive corporate officers, without which they might not have accepted their office.

Internal control and risk management cannot, however, absolutely guarantee that these risks will be totally eliminated and that the Company's objectives will be achieved.

16.5.2 Organisation of internal control

The internal control system is based on a clear organisation of responsibilities, standards, resources and on the procedures implemented.

16.5.2.1 Quality policy

The Group's quality policy is based on a Quality Management System (QMS) set out in a documented system accessible to all employees *via* the intranet. It is implemented by the Quality and Regulatory Affairs Department.

The quality policy, the entry point for the Group's quality objectives, defines QMS organisational principles and procedures, as well as cross-referencing applicable standards for the development, marketing and use of products.

The Group is assessed on an annual basis by an accredited external body.

16.5.2.2 Definition of powers and responsibilities

An organisation memo, regularly updated by Executive Management, defines internal organisation, division of tasks and line management within the Group.

The Finance Department also updates the financial authority limits and responsibilities of managers and establishment heads.

These delegations of authority define the operations that are subject to approval from, or prior notification of, the Group's management, with particular regard to general policy decisions (strategic decisions, external communications, intellectual property, legal disputes and decisions), human resources and pay, financial operations and management (contracts, banks and financial transactions), investments.

Executives responsible for operations are authorised to prepare decisions and negotiate purchases or service provisions. Purchase/service commitments are monitored and then reconciled with invoices and delivery notes for goods before payment is approved. Most payments are made by electronic transfer validated by a double electronic signature.

16.5.2.3 Internal control on accounting and financial information

Company accounting and financial internal control is just one component of the overall internal control system. It covers the entire process of producing and reporting the Company's accounting and financial information and aims to fulfil requirements in terms of the security, reliability, availability and traceability of the information.

Accounting and financial internal control aims to ensure that:

- published accounting and financial information complies with applicable regulations;
- instructions and guidelines set by Executive Management are applied;
- Assets are protected;
- Fraud and accounting and financial irregularities are prevented and detected;

- the information disseminated and used internally for oversight and monitoring purposes is reliable; insofar as it is used to prepare published accounting and financial information;
- financial statements and other information published on the market is reliable.

16.5.2.4 Organisation of the Accounting and Finance department

Finance is managed internally by the Chief Administrative & Financial Officer

The Company is keen to separate its production activities from oversight of financial statements, and uses independent experts to assess some complex accounting items (Research tax credits, pension commitments, BSA/BSPCE valuation) and/or subjective assumptions.

Payroll is dealt with by an external specialist firm. The consolidated financial statements prepared according to IFRS, produced with the help of a specialist independent accounting firm, are audited by the Group's co-statutory auditors.

The Administration and Finance Department reports to the Chief Executive Officer direct.

16.5.2.5 Budget process and monthly reporting

The accounting system set up by the Company is based on French accounting standards. The Company prepares an annual budget. The Company prepares a "monthly operating report", including an operating account, and business and cash positions. These items are presented to the Executive Committee, the *management committees* and to each meeting of the Board of Directors. The Company tracks the budget and makes regular updates.

16.5.2.6 Information system and tools

The Information Systems Department guarantees the security and continuity of the information system. On this basis, it defines applicable security strategy and principles in its Information Systems Security Policy (ISSP), ensures employee best practices and optimal security levels in relation to the risk involved.

The Group's ISSP aims to define principles to protect the Group's information against a wide range of risks (fraud, espionage, accidents, human errors, etc.), to win our customers' trust and comply with legal and regulatory frameworks.

The IT Department provides consistency and a frame of reference, setting out the systems needing protection: the security of information systems, business continuity, the safety of people and goods, and cover for IS security risks.

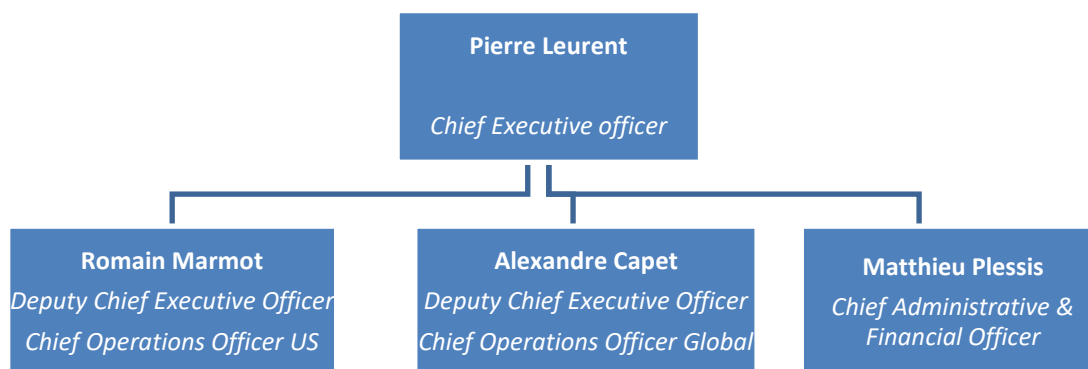
It supports operating staff (training, advice, audits and recommendations) to guarantee compliance with the Group's security provisions.

17. EMPLOYEES

17.1 Human Resources

17.1.1 [Organisational chart as of the date of this Registration Document](#)

The Company's operational management takes the form of an Executive Committee composed of the Chief Executive Officer, the Deputy Chief Executive Officers, and the Chief Administrative & Financial Officer, as shown in the organisational chart below.



The Executive Committee assists the Chief Executive Officer in the Group's strategic and financial guidance. It sets partnership guidelines, supplies the structural framework for medium-term targets, and supervises mergers & acquisitions as well as relations with the Board of Directors and shareholders. This Committee meets at least twice a month.

The Executive Committee is assisted by local Management Committees composed of members of the Executive Committee as well as representatives of all of the Group's departments. This Management Committee is the review and operational decision-making body for the Group's projects. They set out, monitor, and coordinate the action plans identified in the various departments, within their scope of activity. They meet weekly, monitor operational and financial performance, and adjust, if necessary, the Group's operations. The Chief Operations Officers regularly report to the Executive Committee on the actions and decisions taken by local Management Committees.

17.1.2 [Numbers and breakdown of workforce](#)

At 31 December 2018, the Group had 112 employees (of which 93 in France and 19 in the United States).

The Group's headcount at the close of the 2018 financial year may be broken down by department as follows:

	2017	2018
Industrial Operations	58	60
Sales & Marketing	21	25
Medical, Quality & Regulatory	18	18
General Management & Administration	8	10
Total	105	112

17.1.3 [Employee representation](#)

After the elections for a new employee representative body intended to renew the single existing delegation, the second round of which took place on 22 March 2018, the Company established an Economic and Social Committee (CSE) based on the new framework set out by the Law of 23 September 2017. The mission of the CSE is to replace all previously-existing employee representative bodies and individual representatives, the Works Council, and the health, safety and working conditions committee in the Company.

17.2 Shareholding and stock options of corporate officers

See Section 21.1.4.1 of the Registration Document, "*Transferable securities giving access to the Company's share capital*".

17.3 Employee shareholding in the Company

As of the date of the Registration Document, employee ownership (with the exception of corporate officers) of the Company's share capital stood at 1.17%, on a non-diluted basis, given that the percentage of capital represented by shares owned by Company employees and managed collectively under employee share ownership plans (PEE or FPCE), calculated in accordance with the provisions of Article L. 225-102 of the French Commercial Code, was nil and that shares held direct by employees as a result of free share awards in accordance with Article L. 225-197 of the French Commercial Code, accounted for 0% of the share capital at year-end. This shareholding is essentially constituted by the direct holding of shares by historical founders and managers.

17.4 Profit-sharing and incentive schemes

No profit-sharing or incentive schemes had been set up by the Company as of the date of this Registration Document.

18. MAJOR SHAREHOLDERS

18.1 Allocation of share capital and voting rights

The shareholding table below shows the breakdown of the share capital and voting rights of the Company as of the date of this Registration Document.

	Position as of the date of this Registration Document, on a non-diluted basis		Position as of the date of this Registration Document on a fully-diluted basis ⁽¹⁾	
	Number of shares	% of share capital and voting rights ⁽²⁾	Number of shares after exercise of outstanding dilutive instruments	% of share capital and voting rights after exercise of outstanding dilutive instruments ⁽²⁾
Pierre Leurent*	213,400	2.82%	370,396	4.40%
Other	206,149	2.72%	749,813	8.91%
Total Management	419,549	5.54%	1,120,209	13.31%
Bpifrance Participations *	1,567,582	20.69%	1,567,582	18.62%
SHAM Innovation Santé	975,218	12.87%	975,218	11.58%
CM-CIC Innovation *	821,508	10.84%	821,508	9.76%
LBO France Gestion * ⁽⁴⁾	609,839	8.05%	609,839	7.24%
Vesalius Biocapital II SA Sicar *	544,282	7.18%	544,282	6.47%
Cap Décisif Management ⁽³⁾	315,888	4.17%	315,888	3.75%
Qualcomm Inc.	55,297	0.73%	55,297	0.66%
Kreos	-	0.00%	70,000	0.83%
Total - Financial investors	4,889,614	64.54%	4,959,614	58.91%
Other shareholders/consultants/employees holding registered shares	116,498	1.54%	188,863	2.24%
Free Float	2,124,756	28.05%	2,124,756	25.31%
All other shareholders	2,266,498	29.92%	2,338,863	27.78%
Treasury shares	25,244	0.33%	25,244	0.30%
TOTAL	7,575,661	100%	8,418,686	100%

* Members of the Company's Board of Directors

(1) The figures in these columns are disclosed on the basis of fully-diluted capital, i.e. on the assumption that each of the share subscription options in circulation is exercised and each of the warrants and founders' stock options are exercised (see Section 21.1.4, "Transferable securities giving access to the Company's share capital" of the Registration Document).

(2) As of the date of this Registration Document, the percentage of voting rights is identical to the percentage of share capital held, it being however specified, that as from the second anniversary date of the initial listing of the Company's shares on the regulated market of Euronext in Paris, the fully paid-up shares for which evidence is shown of individual registration in the same shareholder's name for at least two years from that date will have double voting rights.

(3) Through the Cap Decisif, Cap Decisif 2, and G1J funds of which it is the management company.

(4) Through the Services Innovants Santé et Autonomie (SISA) fund, of which it has been the management company since the acquisition of the management company Innovation Capital.

(5) Treasury shares under the liquidity agreement signed with Oddo Corporate Finance, or 25,244 shares as of 31 March 2019.

In the year ended 31 December 2018, the AMF received the following notifications that thresholds had been crossed:

- by letter received on 5 June 2018, Bpifrance stated that, as a result of the Company being listed on the stock market, on 31 May 2018 it held, indirectly via the intermediary of Bpifrance Participations, 1,781,867 Voluntis shares representing the same number of voting rights, or 23.55% of the Company's share capital and voting rights; and

- by letter received on 6 June 2018, the Caisse des Dépôts et Consignations stated that, as a result of the Company being listed on the stock market, on 31 May 2018 it held, indirectly via the intermediary of Bpifrance Participations, 1,781,867 Voluntis shares representing the same number of voting rights, or 23.55% of the Company's share capital and voting rights; and

The Company is not aware of any thresholds being crossed between 31 December 2018 and the date of the Registration Document.

18.2 Stock market information

The Company's shares were admitted to trading on the Paris Euronext regulated market (Compartment C) on 30 May 2018, under the ISIN Code FR 0004183960 and the mnemonic, VTX.

They were then listed at €12.84 at market closing. The shares reached their highest price of €14.00 on 30 May 2018 and their lowest price of €4.45 on 19 December 2018. The shares ended 2018 at €4.99.

In 2018, an average of 1,745 shares were traded per day.



18.3 Substantial shareholders not represented on the Board of Directors

As of the date of this Registration Document, SHAM Innovation Santé and Cap Décisif Management, through the funds that each company manages, hold more than 5% of the Company's share capital and are not represented on the Board of Directors.

18.4 Voting rights of the major shareholders

As of the date of this Registration Document, the voting rights of each shareholder are equal to the number of shares held by each of them, with the clarification, however, that as from the second anniversary date of the initial listing of the Company's shares on the regulated market of Euronext in Paris, those fully paid-up shares for which evidence is shown of individual registration in the same shareholder's name for at least two years from that date will have double voting rights.

18.5 Control of the Company

As of the date of this Registration Document, no shareholder has control over the Company as defined in Article L. 233-3 of the French Commercial Code.

With the exception of the presence of Nicolas Cartier, Viviane Monges, Jan Berger and Roberta Herman, independent members of its Board of Directors, and the procedure of regulated agreements, the Company has not put any measures in place with a view to ensuring that any control over it is not improperly exercised.

18.6 Agreements that can result in a change in control

As far as the Company is aware, there is no agreement that, if implemented, could result in a change of control.

18.7 Status of pledged shares of the Company

To the Company's knowledge, none of its shares have been pledged.

18.8 Items likely to have an impact in the event of a public offering

18.8.1 [Structure of the Company's share capital](#)

See Section 18.1 **Erreur ! Source du renvoi introuvable.** of the Registration Document.

18.8.2 [Restrictions on voting rights and share transfers under the Articles of Association or clauses of agreements brought to the Company's attention in accordance with Article L. 233-11 of the French Commercial Code](#)

Non applicable

18.8.3 [Direct or indirect capital interests in the Company of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code](#)

See Section 18.3 of the Registration Document.

18.8.4 [List of holders of any securities conferring special rights of control and a description of these securities](#)

Non applicable

18.8.5 [Control mechanisms provided for under any employee shareholding system, when the rights of control are not exercised by said employees](#)

Non applicable

18.8.6 [Agreements between shareholders of which the Company is aware and which may result in restrictions on share transfers and the exercise of voting rights](#)

As far as the Company is aware, there are no restrictions on the transfer of its shares and the exercise of its voting rights, given that under the Shareholders' Agreement, the parties agree to coordinate share disposals to prevent such disposals from creating any market imbalance (see Section 14.2 of the Registration Document), that would be likely to have a significantly adverse effect on the Voluntis share price.

18.8.7 [Rules on the Appointments and replacement of members of the Board of Directors as well as on the amendment of the Company's Articles of Association;](#)

The rules on the appointment and replacement of members of the Board of Directors, and on the amendment of the Company's Articles of Association are those laid down by law, as well as, for some historical shareholders, by the Shareholders' Agreement (see Section 14.2 of the Registration Document).

[18.8.8 Powers of the Board of Directors, in particular, with regard to the issue or buyback of shares](#)

See Section 21.1.3 of the Registration Document.

[18.8.9 Agreements signed by the Company that would be amended or terminated by a change of control of the Company](#)

The agreement signed with Sanofi on the Diabeo solution, gives Sanofi the option to withdraw from the contract in the event of a transaction affecting the Company's capital and resulting in its control being taken over by one of Sanofi's direct competitors.

The agreement signed with Roche Diagnostics, provides for access to Medpassport platform source codes in the event of a change of control of the Company.

[18.8.10 Agreements providing for compensation for Board members or employees, if they resign or are made redundant without just cause or if their employment ceases because of a takeover bid](#)

One American employee would be entitled, in the event of redundancy without just cause or subsequent to a change of control of the Group, to compensation of three months' salary, plus two weeks for every full year of service, and to keep his health cover.

19. RELATED-PARTY TRANSACTIONS

19.1 Intra-group agreements

See Section 7.3 of the Registration Document.

19.2 Related-party transactions

Regulated agreements entered into during the 2017 and 2018 financial years are listed in the special reports of the Statutory Auditors in Section 19.3 of the Registration Document, below.

In addition, Pierre Leurent, Romain Marmot, and Alexandre Capet have entered into an employment contract, for the first two, with Voluntis, Inc., and for the latter, with the Company (see Section 16.2 of the Registration Document).

19.3 Statutory Auditors' reports on regulated agreements

19.3.1 [Special report of the Statutory Auditors on regulated agreements established in relation to the financial year ended 31 December 2017](#)

Voluntis

Assemblée générale d'approbation des comptes de l'exercice clos le 31 décembre 2017

Rapport spécial du commissaire aux comptes sur les conventions réglementées

ERNST & YOUNG et Autres

Voluntis

Assemblée générale d'approbation des comptes de l'exercice clos le 31 décembre 2017

Rapport spécial du commissaire aux comptes sur les conventions réglementées

A l'Assemblée Générale de la société Voluntis,

En notre qualité de commissaire aux comptes de votre société, nous vous présentons notre rapport sur les conventions réglementées.

Il nous appartient de vous communiquer, sur la base des informations qui nous ont été données, les caractéristiques, les modalités essentielles ainsi que les motifs justifiant de l'intérêt pour la société des conventions dont nous avons été avisés ou que nous aurions découvertes à l'occasion de notre mission, sans avoir à nous prononcer sur leur utilité et leur bien-fondé ni à rechercher l'existence d'autres conventions. Il vous appartient, selon les termes de l'article R. 225-58 du Code de commerce, d'apprécier l'intérêt qui s'attachait à la conclusion de ces conventions en vue de leur approbation.

Par ailleurs, il nous appartient, le cas échéant, de vous communiquer les informations prévues à l'article R. 225-58 du Code de commerce relatives à l'exécution, au cours de l'exercice écoulé, des conventions déjà approuvées par l'assemblée générale.

Nous avons mis en œuvre les diligences que nous avons estimé nécessaires au regard de la doctrine professionnelle de la Compagnie nationale des commissaires aux comptes relative à cette mission.

Conventions soumises à l'approbation de l'assemblée générale

Nous vous informons qu'il ne nous a été donné avis d'aucune convention autorisée et conclue au cours de l'exercice écoulé à soumettre à l'approbation de l'assemblée générale en application des dispositions de l'article L. 225-86 du Code de commerce.

Conventions déjà approuvées par l'assemblée générale

Nous vous informons qu'il ne nous a été donné avis d'aucune convention déjà approuvée par l'assemblée générale dont l'exécution se serait poursuivie au cours de l'exercice écoulé.

Paris-La Défense, le 27 mars 2018

Le Commissaire aux Comptes

ERNST & YOUNG et Autres

Franck Sebag

19.3.2 [Rapport spécial du commissaire aux comptes sur les conventions réglementées établi au titre de l'exercice clos le 31 décembre 2018](#)

RBB BUSINESS ADVISORS

ERNST & YOUNG et Autres

Voluntis

Assemblée générale d'approbation financial statements for the year ended 31 décembre 2018

Rapport spécial des commissaires aux comptes sur les conventions et engagements réglementés

RBB BUSINESS ADVISORS
113 bis, rue de l'Université
75007 Paris
S.A. au capital de € 150.000
414 202 341 R.C.S. Paris

Commissaire aux Comptes
Membre de la compagnie
régionale de Paris

ERNST & YOUNG et Autres
Tour First
TSA 14444
92037 Paris-La Défense cedex
S.A.S. à capital variable
438 476 913 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

Voluntis

Assemblée générale d'approbation des comptes de l'exercice clos le 31 décembre 2018

Rapport spécial des commissaires aux comptes sur les conventions et engagements réglementés

A l'Assemblée Générale de la société Voluntis,

En notre qualité de commissaires aux comptes de votre société, nous vous présentons notre rapport sur les conventions et engagements réglementés.

Il nous appartient de vous communiquer, sur la base des informations qui nous ont été données, les caractéristiques, les modalités essentielles ainsi que les motifs justifiant de l'intérêt pour la société des conventions et engagements dont nous avons été avisés ou que nous aurions découverts à l'occasion de notre mission, sans avoir à nous prononcer sur leur utilité et leur bien-fondé ni à rechercher l'existence d'autres conventions. Il vous appartient, selon les termes de l'article R. 225-31 du Code de commerce, d'apprécier l'intérêt qui s'attachait à la conclusion de ces conventions et engagements en vue de leur approbation.

Par ailleurs, il nous appartient, le cas échéant, de vous communiquer les informations prévues à l'article R. 225-31 du Code de commerce relatives à l'exécution, au cours de l'exercice écoulé, des conventions et engagements déjà approuvés par l'assemblée générale.

Nous avons mis en œuvre les diligences que nous avons estimé nécessaires au regard de la doctrine professionnelle de la Compagnie nationale des commissaires aux comptes relative à cette mission.

Conventions et engagements soumis à l'approbation de l'assemblée générale

Nous vous informons qu'il ne nous a été donné avis d'aucune convention ni d'aucun engagement autorisé et conclu au cours de l'exercice écoulé à soumettre à l'approbation de l'assemblée générale en application des dispositions de l'article L. 225-38 du Code de commerce.

Conventions et engagements déjà approuvés par l'assemblée générale

Nous vous informons qu'il ne nous a été donné avis d'aucune convention ni d'aucun engagement déjà approuvés par l'assemblée générale dont l'exécution se serait poursuivie au cours de l'exercice écoulé.

Paris et Paris-La Défense, le 21 mars 2019

Les Commissaires aux Comptes

RBB BUSINESS ADVISORS

ERNST & YOUNG et Autres

Jean-Baptiste Bonnefoux

Franck Sebag

20. FINANCIAL INFORMATION

20.1 Consolidated financial statements prepared according to the IFRS for the financial year ended 31 December 2018

CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

Consolidated statement of profit or loss

In € thousands	Note	Years ended December 31	
		2018 ⁽¹⁾	2017
Revenue	4.1	4,533	7,302
Other income		637	1,095
Total operating income		5,170	8,396
Purchases & external expenses	4.2	<6,606>	<5,764>
Staff costs	4.3	<12,245>	<10,423>
Taxes & duties		<311>	<284>
EBITDA		<13,992>	<8,075>
Depreciation and amortisation, net	4.5	<1,828>	<1,522>
Provisions, net	4.5	<1>	<28>
Current operating income		<15,819>	<9,625>
Other non-recurring operating income and expenses		308	-
Operating income		<15,512>	<9,625>
Cost of net financial debt	4.6	<568>	<588>
Finance income		141	165
Income tax (expense)	4.7	3	22
NET INCOME		<15,935>	<10,026>
Net income – Equity holders of the parent		<15,935>	<10,026>
Net Income - non-controlling interests			
Earnings per share (in €)	4.8	<2.48>	<2.15>

Consolidated statement of other comprehensive income

In € thousands	Years ended December 31	
	2018 ⁽¹⁾	2017
Net income	<15,935>	<10,026>
Other comprehensive income/loss to be reclassified to profit or loss	(24)	<24>
Remeasurement gains (losses) on defined benefit plans	<24>	<1>
Income tax effect		
Other comprehensive income/loss to be reclassified to profit or loss	(58)	<58>
Exchange differences on translation of foreign operations	<58>	152
TOTAL COMPREHENSIVE INCOME	<16,018>	<9,875>

⁽¹⁾ The Group began applying IFRS 15 on 1 January 2018. 2017 comparative information has not been restated, following the modified retrospective transition method.

Consolidated statement of financial position

Assets (in € thousands)	Note	Years ended December 31	
		2018 ⁽¹⁾	2017
Net intangible assets	5.1	1,901	2,489
Net tangible assets	5.2	563	764
Non-current financial assets	5.3	253	241
Other non-current assets	5.4	1,016	-
Non-current assets		3,732	3,494
Trade and other receivables	5.4	1,505	299
Current financial assets		91	
Other current assets	5.4	5,445	2,322
Cash and cash equivalents	5.5	19,783	1,845
Current assets		26,823	4,466
Total assets		30,555	7,960

Liabilities and shareholders' equity (in € thousands)	Note	Years ended December 31	
		2018 ⁽¹⁾	2017
Capital		758	480
Share premium		70,354	35,752
Retained earnings		<37,876>	<27,334>
Income/(loss) of the year		<15,935>	<10,026>
Equity attributable to equity holders of the parent		17,301	<1,127>
Non-controlling interests			
Shareholders' equity	5.6	17,301	<1,127>
Non-current financial debts	5.8	2,199	252
Provisions	5.7	207	141
Other non-current liabilities	5.9	3,213	322
Non-current liabilities		5,618	714
Current financial debts	5.8	1,440	4,003
Provisions	5.7	77	77
Trade and other payables	5.10	2,062	1,492
Other current liabilities	5.10	4,057	2,801
Current liabilities		7,636	8,373
Total liabilities and equity		30,555	7,960

⁽¹⁾ The Group began applying IFRS 15 on 1 January 2018. The 2017 comparative information has not been restated, following the modified retrospective transition method.

Statement of consolidated cash flow

In € thousands	Note	Years ended December 31	
		2018 ⁽¹⁾	2017
Net income		<15,935>	<10,026>
Depreciation, amortisation and provisions	4.5	1,868	1,550
Share-based payment transaction expense	4.3	613	351
Other non-cash adjustments		<164>	<177>
Capital gains and losses on disposals		3	
Cost of net financial debt	4.6	552	588
Deferred taxes, net	4.7	<3>	<22>
Net change in operating working capital requirements		(1,660)	2,329
Change in trade and other receivables	5.4	<2,120>	3,076
Change in trade and other payables	5.10	460	<737>
Cash flow generated by operations		<14,726>	<5,396>
INVESTMENT ACTIVITIES			
Proceeds/(purchase) from/(of) tangible and intangible assets	5.1 and 5.2	<1,041>	<1,769>
Acquisitions of current financial assets		<296>	<383>
Proceeds/(purchase) from/(of) non-current financial assets			251
Cash flow from investing activities		<1,336>	<1,900>
FINANCING ACTIVITIES			
Proceeds from capital increase		27,675	25
Proceeds from borrowings	5.8	7,550	3,550
Repayment of borrowings	5.8	<802>	<236>
Interests paid		<429>	
Cash flow from financing activities		33,993	3,339
CHANGE IN CASH FLOW		17,931	<3 958>
Impact of exchange rate fluctuations		7	<21>
OPENING CASH BALANCE		1,845	5,824
CLOSING CASH BALANCE	5.5	19,783	1,845

⁽¹⁾ The Group began applying IFRS 15 on 1 January 2018. The 2017 comparative information has not been restated, following the modified retrospective transition method.

Statement of changes in equity

In € thousands	Capital	Share premium	Retained earnings	Foreign currency translation reserve	Profit/(loss) for the year	Attributable to equity holders of the parent	Non-controlling interests	TOTAL
Shareholders' equity as of 31 December 2016	423	29,508	<22,914>	<65>	<4,857>	2,096		2,096
Issue of share capital	57	6,244				6,301		6,301
Profit/(loss) of the year – 2016			<4,857>		4,857			
Profit/(loss) of the year – 2017					<10,026>	<10,026>		<10,026>
Deferred tax provision			<1>			<1>		<1>
Share-based payments			351			351		351
Conversion reserve				152		152		152
Shareholders' equity as of 31 December 2017	480	35,752	<27,421>	87	<10,026>	<1,127>		<1,127>
Issue of share capital	277	34,602				34,880		34,880
Profit/(loss) of the year – 2017			<10,026>		10,026			
Profit/(loss) of the year – 2018					<15,935>	<15,935>		<15,935>
Deferred tax provision			<24>			<24>		<24>
Share-based payments			613			613		613
OC KREOS			216			216		216
Cancellation of treasury shares			<195>			<195>		<195>
Conversion reserve				<50>		<50>		<50>
IFRS 15			<1,077>			<1,077>		<1,077>
Shareholders' equity as of 31 December 2018	758	70,354	<37,913>	36	<15,935>	17,301		17,301

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Contents

NOTE 1:	<u>Description of the Group and its business</u>	
1.1.	<u>The Voluntis Group</u>	
1.2.	<u>Key events during the year</u>	
NOTE 2:	<u>Scope of consolidation</u>	
2.1.	<u>The Voluntis Company</u>	
2.2.	<u>List of consolidated entities</u>	
2.3.	<u>Consolidation methods</u>	
NOTE 3:	<u>Accounting principles applied by the Group and declaration of conformity</u>	
3.1.	<u>Presentation of the first IFRS consolidated financial statements</u>	 Erreur ! Signet non défini.
3.2.	<u>Declaration of conformity</u>	 Erreur ! Signet non défini.
3.3.	<u>Going concern</u>	 Erreur ! Signet non défini.
3.4.	<u>Accounting judgements and estimates used to prepare the financial statements</u>	... Erreur ! Signet non défini.
3.5.	<u>Functional currencies and currency in which the consolidated financial statements are presented</u>	Erreur ! Signet non défini.
3.6.	<u>Intangible assets</u>	 Erreur ! Signet non défini.
3.7.	<u>Tangible assets</u>	 Erreur ! Signet non défini.
3.8.	<u>Impairment of assets</u>	 Erreur ! Signet non défini.
3.9.	<u>Financial assets</u>	 Erreur ! Signet non défini.
3.10.	<u>Capital</u>	 Erreur ! Signet non défini.
3.11.	<u>Share-based payments</u>	 Erreur ! Signet non défini.
3.12.	<u>Financial liabilities</u>	 Erreur ! Signet non défini.
3.13.	<u>Conditional advances</u>	 Erreur ! Signet non défini.
3.14.	<u>Provisions</u>	 Erreur ! Signet non défini.
3.15.	<u>Revenue</u>	 Erreur ! Signet non défini.
3.16.	<u>Leases</u>	 Erreur ! Signet non défini.
3.17.	<u>Income tax</u>	 Erreur ! Signet non défini.
3.18.	<u>Segment reporting</u>	 Erreur ! Signet non défini.
3.19.	<u>Other operating income and expense</u>	 Erreur ! Signet non défini.
NOTE 4:	<u>Notes to the consolidated income statement</u>	 Erreur ! Signet non défini.
4.1.	<u>Operating income</u>	 Erreur ! Signet non défini.
4.2.	<u>External expenses</u>	 Erreur ! Signet non défini.
4.3.	<u>Staff costs</u>	 Erreur ! Signet non défini.
4.4.	<u>Share-based payments</u>	 Erreur ! Signet non défini.
4.5.	<u>Depreciation, amortisation</u>	 Erreur ! Signet non défini.
4.6.	<u>Cost of net financial debt</u>	 Erreur ! Signet non défini.
4.7.	<u>Income tax</u>	 Erreur ! Signet non défini.
4.8.	<u>Net earnings per share</u>	 Erreur ! Signet non défini.
Note 5:	<u>Notes to the consolidated statement of financial position</u>	 Erreur ! Signet non défini.

5.1. <u>Intangible assets</u>	Erreur ! Signet non défini.
5.2. <u>Tangible assets</u>	Erreur ! Signet non défini.
5.3. <u>Other non-current financial assets</u>	Erreur ! Signet non défini.
5.4. <u>Trade and other receivables</u>	Erreur ! Signet non défini.
5.5. <u>Cash</u>	Erreur ! Signet non défini.
5.6. <u>Share capital</u>	Erreur ! Signet non défini.
5.7. <u>Provisions for contingent liabilities and expenses</u>	Erreur ! Signet non défini.
5.8. <u>Interest-bearing loans</u>	Erreur ! Signet non défini.
5.9. <u>Current liabilities</u>	Erreur ! Signet non défini.
5.10. <u>Fair value of financial assets and liabilities</u>	Erreur ! Signet non défini.

NOTE 6: Management and measurement of financial risks Erreur ! Signet non défini.

6.1. <u>Interest rate risk</u>	Erreur ! Signet non défini.
6.2. <u>Liquidity risk</u>	Erreur ! Signet non défini.
6.3. <u>Credit risk</u>	Erreur ! Signet non défini.
6.4. <u>Exchange rate risk</u>	Erreur ! Signet non défini.

Note 7: Other information..... Erreur ! Signet non défini.

7.1. <u>Off-balance sheet commitments</u>	Erreur ! Signet non défini.
7.2. <u>Commitments linked to operating leases</u>	Erreur ! Signet non défini.
7.3. <u>Headcount</u>	Erreur ! Signet non défini.
7.4. <u>Related-party transactions</u>	Erreur ! Signet non défini.
7.5. <u>Compensation of senior executives</u>	Erreur ! Signet non défini.
7.6. <u>Post-closing events</u>	Erreur ! Signet non défini.

NOTE 1 : DESCRIPTION OF THE GROUP AND ITS BUSINESS

1.1 The Voluntis Group

The Voluntis Group ("the Group") includes the Voluntis S.A. Company, established in 2001, and its US subsidiary, Voluntis Inc, incorporated in September 2012. The Group develops and markets therapeutic software to help patients with chronic conditions and improve treatment outcomes.

Our mobile app and web-based digital solutions deliver personalised recommendations directly to patients and their care teams. Uses include dose adjustment, managing side effects, monitoring symptoms and automatic remote analysis of patient results. The recommendations are generated immediately by digitised medical algorithms built on sound scientific intelligence and reinforced by multiple security regulations. While our digital therapeutics are new-generation health solutions, they are classified as healthcare products, which must be approved in clinical trials and submitted for regulatory approval (EC marking in France, FDA approval in the United States). They are available on medical prescription and may be eligible for reimbursement by payers.

Voluntis has two therapeutic solutions for diabetes, Insulia® and Diabeo®, both of which are in the marketing phase, following an extensive clinical trial programme conducted in partnership with Sanofi and the French centre for diabetes research and treatment, CERITD. Insulia® is now in the process of being launched through two complementary channels: direct sales by approaching payer organisations, and indirect sales through non-exclusive distribution partners. Diabeo® is intended for type 1 and type 2 diabetes (T1D and T2D) patients treated on a multi-injection or insulin pump regimen. It has regulatory approval in Europe and is being marketed by Sanofi.

Our oncology offer is under development. The aim of the solutions is to improve patient adherence to their treatment regime. Voluntis is developing a therapeutic solution targeting a range of different cancers, as well as specific solutions under partnership agreements with the pharmaceutical industry.

1.2 Key events during the year

Commercial and business development

Voluntis began the commercial launch in France and North America of its Diabeo® and Insulia® solutions in January 2018, together with its partners. In the United States, the Group is pursuing the creation of its direct sales team with paying bodies, which is reflected in hiring in the sales, marketing, and medical fields.

At the same time, the Group has extended its marketing partnerships in the United States. As such, on 9 January 2018 a new partnership was announced with Welldoc.

In Oncology, the Group met the Food & Drug Administration (the "FDA") in January 2018 at a pre-submission meeting, to lay out the regulatory approval process for its multi-cancer monitoring platform.

Moreover, also in oncology, in March 2018 the Group announced that it was extending its partnership with Roche, with a view to developing and marketing a multi-indication solution in France.

The Group actively participates in the sectoral work of the Digital Therapeutics Alliance.

Finally, on 3 May 2018, the Company entered into an agreement with a US payer, WellDyneRx (Pharmacy Benefit Manager managing approximately 850,000 insured persons in the targeted commercial segment). This agreement covers the promotion, price and reimbursement conditions of its Insulia solution by WellDyneRx in the United States of America. Insulia's terms and conditions of coverage set out in this agreement are in line with standard terms and conditions applied to direct marketing to US payers.

Financing

On 29 May 2018, the Company announced that it had successfully completed an IPO on the Euronext Paris regulated market and raised €30.1 million (gross, excluding related costs).

The convertible bonds subscribed in July 2017 and January 2018 and the corresponding accrued interest were converted into share capital at the time of the Company's IPO.

In addition, under a Venture Loan Agreement and a Bond Issue Agreement entered into by the Company and Kreos Capital V (UK) Ltd. ("Kreos") on 11 April 2018, the latter paid the nominal amount of €4 million, on 1 May 2018, of the bonds issued by the Company. Similarly, Kreos Capital V (Expert Fund) L.P. subscribed 70,000 warrants (the BSA2018-Kreos), allocated by the Company in consideration for these bonds.

At end-December 2018, the Group, on its own or via its US subsidiary, had €19.8 million in available cash.

Product developments and Research & Development

The Group continued investing in its two main therapeutic focuses by:

- enhancing the functionalities and coverage of its diabetes products to hold on to its leadership position and open new geographic and demographic market segments; and
- developing its cancer treatment platform, Theraxium Oncology.

Governance

By means of a resolution of the Extraordinary General Meeting of 11 April 2018, shareholders approved the change in the Company's method of administration and management and agreed to move from being a French société anonyme (limited liability company) with supervisory and management boards to being a French société anonyme with a board of directors.

This change was accompanied by the reappointment of some officers and by the arrival of three new independent directors so that the composition of the governance bodies complies with the regulations and requirements of the MiddleNext Code, as chosen by the Company.

NOTE 2 : SCOPE OF CONSOLIDATION

2

2.1 The Voluntis Company

Voluntis is a French Société Anonyme with a Board of Directors, subject to the regulations applicable to commercial companies, whose registered office is at 58, Avenue de Wagram, 75017 Paris, France.

Voluntis is the ultimate parent company of the Group. The sole subsidiary under the exclusive control of Voluntis is fully consolidated. The Company and its Subsidiary make up the Group.

2.2 List of consolidated entities

Entities	Head office	% control 31/12/2018	% interest 31/12/2018	% of control 31/12/2017	% of interest 31/12/2017
Voluntis SA	58, Avenue de Wagram, 75017 Paris	Parent Company	100%	Parent Company	100%
Voluntis Inc.	125 Cambridge Park Drive, Cambridge MA 02140 - USA	100%	100%	100%	100%

2.3 Consolidation methods

Entities in which Voluntis S.A. exercises, or has the power to exercise directly or indirectly are fully consolidated.

Subsidiaries are fully consolidated from the date of acquisition, being the date on which the Group obtains control, and continue to be consolidated until the date it ceases. The financial statements of the Group and the consolidated entities were prepared on the same closing date, namely 31 December 2018. If necessary, adjustments are made to the subsidiaries' financial statements so that their accounting methods are in line with the Group's accounting principles.

NOTE 3 : ACCOUNTING PRINCIPLES APPLIED BY THE GROUP AND

DECLARATION OF CONFORMITY

Values presented in the consolidated financial statements are expressed in thousands of euros, unless otherwise stated.

3

3.1 Declaration of conformity

In application of European Regulation No. 1606/2002 of 19 July 2002 on international standards, the Group's consolidated financial statements have been prepared according to the standards and interpretations published by the International Accounting Standards Board (IASB) adopted by the European Union and mandatory at the closing of accounts.

This standard, which is available on the European Commission website (http://ec.europa.eu/internal_market/accounting/ias_fr.htm), incorporates the international accounting standards (IAS and IFRS), the Standing Interpretations Committee - SIC and the International Financial Interpretations Committee - IFRIC).

The general principles and accounting methods and options retained by the Group are described below.

3.2 Accounting principles and methods

The accounting principles used to present the 2018 consolidated financial statements are identical to those used for the annual financial statements for the year ended 31 December 2017, except for the first-time application of the following new standards, amendments, modifications to standards and interpretations adopted by the European Union:

3.2.1 New standards adopted by the European Union and applicable at 1 January 2018:

➤ IFRS 15 - Revenue from contracts with customers

On 28 May 2014, the IASB published a new revenue recognition standard to replace all existing provisions (IAS 18, IAS 11 and associated interpretations). It was adopted by the European Union on 29 October 2016. This new standard introduces a single revenue recognition model for all types of contracts, whatever the business segment.

IFRS 15 introduces an income recognition approach focused on:

- identifying contracts, customers, contract amendments;
- identifying distinct performance obligations (promises made by the supplier), their reference prices (stand-alone selling price), over time or at a given point in time of the transfer of control over performance obligations to the customer;
- determining the transaction price (consideration promised by the customer), its fixed and variable components (and the associated recognition constraint), as well as its allocation to performance obligations.

This new recognition approach is based on the general principle of recognising revenue when control of goods or services is transferred to a customer, either over time, or on a given date.

The revenue recognition principles applied by the Voluntis Group are described in Note 3.15 - Revenue

The impact of the application of IFRS 15 on the financial statements for the 2018 financial year was to add €20 k in revenue and increase operating expenses by €1,119 k. Along with this total net impact of - €1,099 k, carried over into the loss for the period, there was an adjustment to shareholders' equity at the beginning of the period which lowered retained earnings by €1,077 k (See Note 6 – Application of IFRS 15 Reconciliation table).

➤ **IFRS 9 - Financial instruments.**

The standard replaces IAS 39 "Financial instruments: recognition and measurement" and relates to classification and measurement, as well as impairment and hedge accounting for financial assets and liabilities. The new standard is applicable from 1 January 2018.

Classification of financial assets

IFRS 9 allows for a new approach to classifying and measuring financial assets and liabilities. It describes three classes of assets: those measured at amortised cost, those measured at fair value through net profit or loss and those measured through other comprehensive income. These new provisions have no material impact on the way in which the Group recognises its financial assets and liabilities.

Measurement of expected credit loss on trade receivables and contract assets

IFRS 9 introduces a new impairment model and requires the recognition of provisions for impairment based on an expected loss impairment model, while past standards stipulated a model based on known risks. The Group measured the losses incurred over the last few years for its customer portfolio and concluded that the new provisions on impairment of active contracts did not have a material impact on the consolidated financial statements.

The Group has applied IFRS 9 to its consolidated financial statements since 1 January 2018.

➤ **IFRIC 22 "Foreign currency transactions and advance consideration":**

IAS 21 "Effects of changes in foreign exchange rates", specifies the exchange rate to use to record a transaction in a foreign currency when it was initially recognised in the entity's functional currency. The standard does not, however, deal with the issue of the exchange rate to use when an advance payment has been made.

This is why the IFRS interpretations committee prepared this interpretation, which has been ratified by the IASB.

In accordance with paragraphs 21-22 of IAS 21, the transaction date, for the purposes of determining the rate of exchange to use for initial recognition of the asset, the expense or the related income (or part of it) is the date of initial recognition of the non-monetary asset or non-monetary liability arising from the early payment or redemption.

➤ **Annual improvements to IFRS 2014 - 2016 cycle**

The Annual improvements to IFRS 2014 - 2016 cycle make minor amendments to the following three standards:

- IFRS 1: deletion of short-term exemptions for first-time adopters
- IFRS 12: clarification of the scope of the disclosure requirements
- IAS 28: measurement of investments at fair value through profit or loss per investment.

➤ **Amendments to IFRS 2 "Clarifications of classification and measurement of share based payment transactions":**

These amendments, for which application is mandatory for financial years beginning on or after 1 January 2018, clarify:

- the measurement of share plans settled in cash,
- the issue of changing a "cash settled" plan into an "equity settled" plan.

[3.2.2 New standards adopted by the European Union whose application was not mandatory at 31 December 2018:](#)

The Group has not opted for an early application of standards and interpretations whose application is not mandatory for financial year 2018.

➤ **IFRS 16 - Leases.**

The IASB published a new standard - IFRS 16 - on the recognition of leases in January 2016. This standard represents a major change in how leases are recognised and sets out a single lessee accounting model requiring lessees to recognise assets and liabilities for all leases except for those of less than 12 months or for which the underlying asset is of low value.

According to this model, the depreciation and amortisation of the asset will be recognised as an operating expense and the cost of debt to the lessor as a financial expense.

IFRS 16 is applicable as from 1 January 2019 and the Group has decided not to apply it early.

The Group identified its leases and measured its debt from leases.

Under this new standard, the sum of non-discounted future lease commitments, stood at €4,059 k at 31 December 2018. Its application would be reflected in an increase in the Group's debts of €2,078 k and an increase in fixed assets of €1,975 k net.

Going concern

The going concern assumption was retained by the Group's Management based on the following items:

Management has forecast the future cash flows required to market its products. These forecasts show that the Company currently has the necessary financing for its development during the 12 months following the closing date of these financial statements.

In particular, management has taken account of the following probable sources of financing in 2019:

- the drawdown of additional tranches provided for in the agreement signed with Kreos for an amount which may be up to €3 million;

- the collection of a research tax credit for 2017 and the ability to use the 2018 research tax credit when it becomes due.

In the longer term, according to its sales growth, the Group will look to obtain future funding in addition to new revenue from commercial agreements, particularly by putting in place new lines of borrowing, but also through recourse to the market involving current shareholders and new investors.

Thus, the Group believes that it has sufficient resources to pursue its activities for the foreseeable future. For this reason, it has prepared its financial statements according to the going concern principle.

3.3 Accounting judgements and estimates used to prepare the financial statements

The preparation of financial statements requires Management to exercise judgement, and use estimates and assumptions that affect the reported amounts of assets and liabilities at the reporting date as well as on items of profit (loss) for the period. These estimates take into account the economic data that are subject to changes over time and entail uncertainties. The underlying estimates and assumptions are made based on past experience and other factors which are considered reasonable in light of the circumstances. Therefore, they serve as a basis for exercising the judgement required to determine the accounting values of assets and liabilities, which may be obtained directly from other sources. Actual values may differ from the estimated values.

The measurement of certain balances of the balance sheet and the income statement requires the use of assumptions, estimates or evaluations that have an impact on the application of the accounting methods and on the declared amounts of assets, liabilities, income and expenses. These estimates and assumptions are reviewed regularly. Changes to accounting estimates are recognised in the period during which the changes took place.

The areas for which assumptions and estimates are significant with regards to the Group's financial statements primarily include: estimation of the allocation of the contractual revenues in return for the Group's obligations under its customer contracts, the lifecycle of the products and improvements developed internally, estimation of the feasibility and the resources required to complete the products or projects, fair value of share-based payments and the current and non-current provisions.

3.4 Functional currencies and currency in which the consolidated financial statements are presented

The consolidated financial statements are presented in thousands of euros, the euro is the presentation and functional currency of Voluntis SA, the parent company of the Group. The functional currency of Voluntis Inc. is the US dollar.

Expenses and income in a foreign currency are converted at for their corresponding value on the date of the transaction. Loans and receivables are included in the balance sheet for their corresponding value at the end of the financial year.

The assets and liabilities of companies included in the scope and expressed in foreign currencies are converted into euros using the exchange rate on the closing date, with the exception of the net position which remains at its historic value. The income and expenses of these companies are converted into euros using the average exchange rate over the period. Exchange differences resulting from these conversions are recognised in other comprehensive income under "Foreign currency differences".

The exchange rates for the US dollar used to convert the financial statements of Voluntis Inc. into euros over the 12 months period to 31 December 2018 and 31 December 2017 are as follows:

Currency	2018 Opening rate	2018 Average rate	2018 Closing rate	2017 Opening rate	2017 Average rate	2017 Closing rate
Euro (EUR)	1	1	1	1	1	1
US dollar (USD)	0.833820	0.878426	0.873362	0.948677	0.885206	0.833820

3.5 Intangible assets

3.5.1 [Research and development](#)

Research costs are expensed as incurred. Software development expenditure is recognised as intangible asset when the Group can demonstrate that the criteria are met.

The part recognised as intangible assets is related to the costs allocated to detailed specification activities, programming, testing and software documentation during active marketing that are likely to generate revenue for Voluntis, provided that they meet the activation criteria defined by IAS 38.

The software created is amortised over the useful life of the asset, taking into account the estimated rate of obsolescence and renewal of the functions developed in one year.

The amortisation period for each software is estimated individually. At 31 December 2018, all of the software recorded as an asset was subject to amortisation over three years. Capitalised developments costs are amortised when one of the following occurs:

- signature by Design Output (DO) for products already marketed and covered by regulatory approvals for the version in question;
- when the first regulatory approval is obtained;
- recognition of the first euro in revenue.

The tax saving linked to the research tax credit, on the basis of the eligible portion of the software development costs, will reduce the amount of the assets recorded.

3.5.2 [Other intangible assets](#)

Other intangible assets correspond essentially to the software acquired and amortised over periods estimated between 1 and 3 years depending on the expected useful life time. Intangible assets acquired are recognised as an asset on the balance sheet at the acquisition cost.

3.6 Tangible assets

Tangible assets are valued at their acquisition cost (excluding current maintenance costs), less the accumulated depreciation and impairment. Depreciation is calculated using the straight-line method depending on the asset class over the useful life of the asset in accordance with the taxation legislation in force in France.

The average terms and methods of depreciation for each asset class are the following:

- fixtures and technical facilities: 5-year straight-line;
- computer equipment: 3-year straight-line;
- office equipment and furniture: 5-year straight-line.

3.7 Impairment of tangible and intangible assets

The carrying amounts of the Group's assets are reviewed at each reporting date to assess whether there is any indication that those assets have suffered an impairment loss. If such an indication exists (reduction in value on the market or accelerated obsolescence for example), an impairment test is performed.

The impairment test consists of comparing the carrying amount of the asset or group of assets concerned and its recoverable amount. The recoverable amount of an asset is the highest value between its selling price net of disposal costs and its value in use. The value in use is the discounted value of the estimated future cash flow from the use of the asset and its disposal at the end of its useful life.

Impairment loss is recognised whenever the carrying value of the asset is higher than its recoverable amount.

The recoverable amount must be estimated for each asset taken individually. If this is not possible, IAS 36 requires that a company determines the recoverable amount of the cash generating unit to which the asset belongs.

The assets are then allocated to cash generating units (the smallest identifiable group of assets whose continued use generates cash flows which are largely independent of the cash flows from other assets or groups of assets). The Group has not carried out any growth transaction by means of the acquisition of a company or business and does not present any goodwill on its balance sheet. It is considered as a single cash-generating unit.

An impairment loss recognised for another asset is reversed if there is a change in the estimates used to determine the recoverable amount.

The carrying value of an asset, increased through reversal of an impairment loss, should not be higher than the carrying value which would have been determined, net of depreciation, if no impairment loss had been recognised.

3.8 Financial assets

3.8.1 [Non-current financial assets](#)

The non-current financial assets mainly include security deposits made as part of the activity.

3.8.2 [Trade and other receivables](#)

Trade and other receivables are measured at their nominal value, less allowance for doubtful accounts.

Impairment losses are recognised in the income statement when there is objective evidence that the asset has lost its value. The factors taken into account to identify these potential impairment losses are mainly proven financial difficulties of a creditor or late payments.

3.8.3 [Cash and cash equivalents](#)

Cash and cash equivalents include short term investments (term of investment generally 3 months or less), highly liquid (sale possible at any time without any impact on the asset value), which are readily convertible into known amounts of cash and which are subject to a negligible risk of change in value (with a history that attests to the consistency of their performance).

3.9 Capital

Ordinary and preferred shares are classified in shareholders' equity. The costs of capital operations directly attributable to the issue of shares or new options are recorded in shareholders' equity less the proceeds from the issue, net of tax.

3.10 Share-based payments

Since 2011, the Company has issued share warrants (BSAs), founders' stock options (BSPCEs) stock options (OSAs) and free shares (AGAs).

IFRS 2 indicated, among others, that all equity-settled transactions must be recorded in the financial statement at the time when the corresponding service is rendered.

The Group applied IFRS 2 to all of the equity instruments granted to employees or executives.

The fair value of warrants, options and free shares allocated is recognised in personnel expenses in consideration for an increase in equity under the item "Retained earnings". Fair value is measured on the allocation date and spread over the period during which the employees exercise their options.

3.11 Financial liabilities

A financial liability is either:

- (a) a contractual obligation (i) to deliver cash or another financial asset to another entity; or (ii) to exchange financial assets or financial liabilities with another entity under conditions that are potentially unfavourable to the entity; or
- (b) a contract that will or may be settled in the entity's own equity instruments and is: (i) a non-derivative for which the entity is or may be obliged to deliver a variable number of the entity's own equity instruments; or (ii) a derivative that will or may be settled other than by the exchange of a fixed amount of cash or another financial asset for a fixed number of the entity's own equity instruments.

3.11.1 [Financial liabilities at amortised cost](#)

Interest-bearing borrowings are recognised initially at fair value less attributable transaction costs, where appropriate. After initial recognition, interest-bearing loans and borrowings, are subsequently measured at amortised cost using the effective interest method.

The effective interest rate is the rate that exactly discounts future cash flows until their expiry, to obtain the net value of the loan on the date it was initially recognised. To calculate the effective interest rate of a financial liability, future cash flows are determined based on the maturity of contractual repayments.

3.11.2 [Liabilities measured at fair value through profit or loss](#)

Changes in liabilities measured at fair value through profit or loss are recognised under "Net borrowing costs".

3.12 Conditional advances

The Group may receive financial aid in the form of conditional advances, which are interest free advances, repayable in full or in part based on the recognition by the source of finance of a technical or commercial success of the related project by the financing entity.

The amount resulting from the benefit of having no interest is considered as a grant for the preparation of IFRS financial statements.

Liability was calculated at fair value by discounting, at the estimated market rate, the future flow of disbursements.

3.13 Provisions

3.13.1 [Provisions](#)

Provisions for liabilities and disputes correspond to commitments resulting from various disputes, for which the due date and amount are not known.

A provision is recognised when the Group has a present obligation towards a third-party as a result of a past event, when it is probable that the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation.

The amount recognised is the best estimate of the expenditure needed to settle the obligation.

3.13.2 [Employee commitments: employee benefits](#)

The Group recognises a liability for employee benefits in accordance with the amended IAS 19 standard.

a) *Defined contribution plans*

Contributions made to a defined contribution plan are recorded in expenses when they are incurred.

b) *Retirement benefits*

The Group's commitments with regard to retirement consist of the benefits paid when the employee retires. In accordance with revised IAS 19 "Employee benefits" as part of the defined contributions plan, the commitment is calculated taking into account actuarial assumptions. The Company complies with the Syntec Collective bargaining agreement (engineering offices and consultancy firms). Further, the Group's defined contributions plans are limited to the legal and collective agreement framework in France. The cost of current services (i.e. the period) is presented as employee expenses.

3.14 Revenue

3.14.1 [Revenue recognition](#)

Revenue mainly consists of user licensing fees, set up services , subscriptions (SaaS licences and hosting), support and maintenance services as well as the amounts linked to the operational achievement of contract milestones: Upfront payments, regulatory milestones or clinical success fees.

The Group recognises a customer contract as soon as there is a formalised agreement creating legally enforceable rights and obligations, including terms of payment, the contract has a commercial substance and the collection of consideration is probable. Revenue is recognised when the control of a product or service is transferred to a customer, for an amount that reflects the consideration to which the Group expects to be entitled in exchange for these products or services.

The Group's revenue comes from the sale of its services, combining three main components:

- intellectual property licences;
- development and setup services;
- support and maintenance services.

The rules applied to these categories of revenue are as follows:

General cases:

a. Licences

The "licences" revenue comes from the granting of licences to customers to use Group software.

Where the licence is separate from other service provisions covered by a contract, the Group determines, for each individual contract, whether the licence consists of granting:

- a **right of access** to the intellectual property as it exists throughout the period covered by the licence – in which case the revenue is spread over the shorter of the licence term and the estimated useful life of the intellectual property to which the licence relates,
- or a **right of use** of the intellectual property as it exists at the start of the period in which the customer will be able to use, and benefit from, the licence - in which case the revenue is recognised immediately on that date.

Where the licence is not distinct from other service obligations, the Group determines if the service obligation, including the licence, is satisfied over time or at a specific point in time.

In some cases, the Group must complete specific developments before the licence can be used by the customer. In this event, billing for these developments is considered to be additional licence-related revenue and recognition is postponed until the start of the licence's period of use. The revenue and costs associated with the developments are recognised at the same rate, and over the same term, as licence-related revenue.

Consequently, the application of IFRS 15 spreads revenue over the licence access period.

b. Service provisions

Assistance and advisory services are recognised when the assignment's related deliverables are handed over if they are a promise that is distinct from the licence granted.

If the service provision is not distinguishable from the license granted, it is treated like the specific developments (see supra).

c. Support

The "support" revenue includes hosting, maintenance, and technical, medical and regulatory support services. Revenue is recognised over time during the service period in question because the customer uses the service at the point in time when it is provided by the Group, if this service constitutes a promise that is distinct from the licence granted.

Terms of payment and assets/liabilities related to customer contracts

The terms and conditions of invoicing different obligations included in the commercial contracts may take a variety of forms, including non-refundable down payments, down payments related to the license, milestone payments (regulatory, clinical, linked to market launch, performance, etc.) and one-time or regular licence fees.

If there are disparities between revenue recognised over a given period and recognised invoicing, the Company records deferred income as a liability for the invoicing of items relating to one or more subsequent financial years, or it records future invoices as an asset for performance obligations that have been fulfilled but not yet invoiced.

The Group has been applying IFRS 15 in its consolidated financial statements since 1 January 2018 according to the modified retrospective transition method. The effect of the first-time application of the standard is recognised in shareholders' equity at 1 January 2018.

Regarding down payments and milestone payments related to right of access licences, the consequence of the application of IFRS 15 is that revenue is spread over the term of access to the licence, whereas under IAS 18 this revenue was recognised when the related objectives were achieved. Revenue has now been spread over future periods and recognised, depending on their term, either in current or non-current assets.

Revenue and the costs related to developments prior to the access licence are now deferred until the time when the customer may actually use the licence, and then spread over the term of use of the licence. In contrast, under IAS 18 they were recognised based on the progress of the development project. Revenue and costs are therefore deferred over subsequent financial years.

3.14.2 [Other revenue](#)

Subsidies

Due to its innovative activities, the Group receives subsidies or government grants. Subsidies and grants related to income are presented as part of profit or loss under the "Other operating income section". Subsidies and grants related to assets are presented in the statement of financial position by deducting the subsidies and grants in calculating the carrying amount of the assets.

Research tax credit

The research tax credit (CIR) is granted to companies by the tax authorities to promote technical and scientific research. The expenses incurred by the Group which fulfil the required criteria benefit from a

tax credit that can be offset against income tax returns. Under specific conditions, the unused portion of the CIR can be refunded.

The portion financing research expenditure is recognised under "Other operating income" on the reporting period during which the eligible expenses are incurred. The portion financing development expenditure eligible for capitalisation is deducted in calculating the carrying amount of the assets.

3.15 Leases

Leases for which a significant part of the risks and benefits inherent to ownership are effectively handled by the lessor are classified as operating leases. The payments made under these contracts are recognised in expenses of the reporting period.

3.16 Income tax

The income tax recognised in the consolidated statement of profit and loss includes taxes payable and deferred taxes. Both current and deferred income tax are recognised in the income statement, except when they are related to items directly recognised in equity.

3.16.1 [Current income tax](#)

Current income tax assets and liabilities of the reporting period are measured at the amount expected to be recovered from or paid to the taxation authorities. Tax rates and tax laws used to compute these amounts are those that are enacted, or substantially enacted at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognised directly in equity is recognised in equity and not in the income statement.

Company Value Added Contribution (CVAE) was recognised in tax expenses as permitted by IAS 12.

3.16.2 [Deferred tax](#)

Deferred tax is provided using the liability method on the temporary differences between the tax bases of assets and liabilities, and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognised for all taxable temporary differences.

Deferred tax assets are recognised for all temporary differences, the carry forward of unused tax credits and unused tax losses, to the extent that it is probable that a taxable profit will be available, against which the deductible temporary differences, carry forward of tax losses and unused tax credits can be utilised.

The carrying amount of deferred taxes is reviewed at each closing date and reduced to the extent that it no longer appears probable that sufficient taxable profit will be available to allow all or part of the asset to be utilised.

Deferred taxes and liabilities are measured based on the expected tax rates for the financial year during which the asset will be realised or the liability settled, based on the tax rates (and tax rules) which were adopted or substantially adopted on the closing date.

The deferred taxes relating to items recognised directly in shareholders' equity are recognised in shareholders' equity and not in the income statement.

Deferred assets and liabilities are offset when there is a legally enforceable right to set off tax assets and liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

For 2017 and 2018 reporting periods, the tax rate used to calculate stocks of deferred taxes for Voluntis SA was 28%. With regards to Voluntis Inc. the tax rate used was 35%.

3.17 Segment reporting

The Group operates in a single industry segment: development of digital therapeutic solutions based on its Theraxium platform. The assets, liabilities and operating losses made are primarily located in France.

3.18 Other operating income and expense

These concern a very small amount of income or expense, unusual, abnormal, and uncommon - of significant amounts - disclosed separately in the income statement to improve the understanding of the current operational performance.

NOTE 4 : NOTES TO THE CONSOLIDATED INCOME STATEMENT**2****3****4****4.1 Operating income**

	Years ended December 31	
	2018	2017
Revenue	4,533	7,302
Subsidies	637	1,087
Other income	0	7
Total operating income	5,170	8,396

The Group's revenue includes user licensing fees, set-up services, subscriptions, support and maintenance services, as well as amounts linked to contractual milestones and breaks down as follows:

	Years ended December 31	
	2018	2017
Upfront payment, exclusivity fees, perpetual licences	464	3,701
Development, set-up and integration services	2,016	1,163
SaaS fees, royalties, maintenance & support	2,054	2,438
Total Revenue	4,533	7,302

Revenue by geographic sector breaks down as follows:

In € thousands	Years ended December 31	
	2018	2017
Europe	3,311	5,244
North America	1,140	1,976
Rest of world	82	82
Total Revenue	4,533	7,302

Revenue by therapeutic field breaks down as follows:

In € thousands	Years ended December 31	
	2018	2017
Diabetes	1,159	3,934
Oncology	2,510	2,190
Other	865	1,178
Total Revenue	4,533	7,302

Subsidies primarily consist of the research tax credit, for the portion of expenses recognised as expenses during the year, or €635 k in 2018. The drop of €400 k from the previous year was due to a higher percentage of development expense being activated in 2018 than in 2017 and the resultant allocation of the research tax credit.

4.2 External expenses

External expenses recognised over the last two years break down as follows:

In € thousands	Years ended December 31	
	2018	2017
Outside services	<933>	<925>
<i>Fees and external personnel</i>	<i><1,301></i>	<i><1247></i>
<i>Advertising</i>	<i><275></i>	<i><134></i>
<i>Travel and transportation costs</i>	<i><853></i>	<i><642></i>
<i>Telecoms, internet and postal expenses</i>	<i><843></i>	<i><682></i>
<i>Banking services</i>	<i><15></i>	<i><16></i>
<i>Other miscellaneous external expenses</i>	<i><238></i>	<i><265></i>
Other external expenses	<3,524>	<2,986>
Other operating expenses	<380>	<165>
Subcontracting purchases	<2,465>	<2,294>
Purchases of equipment and supplies not held in inventory	<49>	<76>
Capitalised development costs	745	682
External expenses and other operating expenses	<6,606>	<5,764>

4.3 Staff costs

Staff costs, including share-based payments (see Note 3.4 Share-based payments) are shown in the table below:

	Years ended December 31	
	2018	2017
Wages	(8,535)	(7,858)
Payroll expenses	(3,374)	(3,134)
Share-based payments	(613)	(351)
Capitalised development costs	1,396	920
Cost of executing customer contracts	(1,119)	
Total staff costs	(12,245)	(10,423)

The average number of employees was 107 and 103 people respectively, in 2018 and 2017.

The cost of executing contracts reflects the net costs carried as assets for staff costs carried as assets and relating to elements of customer contracts which have been completed but for which control has not been transferred to the customer in question and the reversal of costs previously activated and relating to goods or services, control over which has been transferred to the buyer over the period.

4.4 Share-based payments

Some employees and corporate executives, subject to the employee's presence in the Group, receive compensation in the form of equity instruments, including share-based payments. The Group issued warrants (BSA), founders' stock options (BSPCE) and stock options (OSA) as follows:

4.4.1 Warrants (BSA):

Name	Date of issue	Subscription price per share	Number issued at 31/12/2018	Number of warrants expired or exercised at 31/12/2018	Number of warrants outstanding at 31/12/2018	Maximum number of shares to be issued
WARRANTS ⁰⁹¹¹	09/09/2011	€7.33	8 000	(8,000)		
WARRANTS ⁰⁹¹²	18/09/2012	€7.33	2,000	(2,000)		
WARRANTS ⁰³¹³	08/03/2013	€7.33	4,100	(4,100)		
WARRANTS ⁰⁶¹⁴	05/06/2014	€8.07	2,000	(2,000)		
WARRANTS ⁰⁷¹⁵	02/07/2015	€8.07	28,284		28,284	28,284
WARRANTS ⁰⁷¹⁵	30/07/2015	€11.00	32,683		32,683	32,683
WARRANTS ⁰⁷¹⁷	17/07/2017	€11.00	22,500		22,500	22,500
BSA ^{KREOS (1)}	11/04/2018	€11.00	70,000		70,000	70,000
WARRANTS ¹⁰¹⁸	25/10/2018	€14.00	75,600		75,600	75,600
TOTAL			245,167	(16,100)	229,067	229,067

⁽¹⁾ Warrants allocated to a third-party as part of financing activities are not included within the scope of IFRS 2 (see Note 4.4.4).

The warrants are convertible into ordinary shares at the rate of one ordinary share per share purchase warrant. All warrants plans are transferable. Warrants are financial instruments that entitle holders to subscribe to ordinary shares of Voluntis SA, at a given price and on a given date, in a fixed proportion.

To estimate the benefit provided, the fair value of the shares is measured on the allocation dates.

4.4.2 Founders' stock options (BSPCE):

Name	Date of issue	Subscription price per share	Number issued at 31/12/2018	Number of warrants expired or exercised at 31/12/2018	Number of warrants outstanding at 31/12/2018	Maximum number of shares to be issued
BSPCE ⁰³¹³	08/03/2013	€7.33	70,900	(70,900)		
BSPCE ⁰⁶¹⁴	05/06/2014	€8.07	132,671	(8,898)	123,773	123,773
BSPCE ⁰⁶¹⁵	01/06/2015	€8.07	15,000		15,000	15,000
BSPCE ⁰⁷¹⁵	30/07/2015	€11.00	206,000	(16,000)	190,000	190,000
BSPCE ⁰⁹¹⁵	30/09/2015	€11.00	38,000	(10,000)	28,000	28,000
BSPCE ⁰⁶¹⁶	13/06/2016	€11.00	75,000		75,000	75,000
BSPCE ⁰⁶¹⁶	22/06/2016	€11.00	128,500	(18,000)	110,500	110,500
TOTAL			759,071	(216,798)	542,273	542,273

Founders' stock options (BSPCEs) can be converted into ordinary shares and each BSPCE entitles the holder to one ordinary share. All of the founders' stock options are non-transferable. A discount for non-transferability has therefore been applied to value the plans issued up to the end of 2014.

To estimate the benefit provided, the fair value of the shares is measured on the allocation dates.

4.4.3 [Stock options \(OSA\):](#)

Name	Date of issue	Subscription price per share	Number of options issued at 31/12/2018	Number of options expired or cancelled at 31/12/2018	Number of options outstanding at 31/12/2018	Maximum number of shares to be issued
Stock options ₀₇₁₇	17/07/2017	€11.00	28,000	(28,000)		
Stock options ₀₅₁₈	30/05/2018	€14.00	36,270	-	36,270	36,270
Stock options ₀₅₁₈	13/06/2018	€14.00	5,000		5,000	5,000
TOTAL			69,270	0	41,270	41,270

The 28,000 stock options (OSA₀₇₁₇) allocated, on the condition that the employee is still working at the Company, at the rate of 25% of the number of options allocated per year counting from when the beneficiary joined the Company, have expired.

The 36,270 options awarded in April 2018 can be exercised as soon as the Company's shares are listed on the stock market and will continue to be exercisable, at the latest, within five (5) or ten (10) years of the grant date and entitle the holder to one ordinary share per option exercised.

The plan awarded in June 2018, for up to 5,000 options, will be exercisable at the rate of 25% of the number of options allocated per year, on the condition that the employee is still working at the Company, and options will continue to be exercisable, at the latest, for up to five (5) years from the grant date and entitle the holder to one ordinary share per option exercised.

4.4.4 [Free share allocations:](#)

Name	Date of allocation	Price of allocation per share	Number of free shares notified at 31/12/2018	Number of shares vested at 31/12/2018	Number of options vesting at 31/12/2018	Maximum number of shares to be issued
AGA ₀₄₁₈	11/04/2018	€0.00	25,415	0	25,415	25,415
TOTAL			25,415	0	25,415	25,415

4.4.5 [Measurement of BSAs, BSPCEs and OSAs](#)

Costs relating to share-based payments are recognised in expenses for the period of service required for beneficiaries to earn rights.

BSAs, BSPCEs and stock options are measured at fair value on the grant date based on a mathematical model commonly used by option markets specialists. This model is based on volatility assumptions relating to the share price, the expected life of the options and the distribution of future dividends, determined by Management.

Warrants (BSAs)

Plan name	WARRANTS 0911	WARRANTS 0912	WARRANTS 0313	WARRANTS 0614	WARRANTS 0715	WARRANTS 0715	WARRANTS 072017	WARRANTS 102018
Date of allocation (Management Board or General Meeting)	09/09/2011	18/09/2012	08/03/2013	05/06/2014	02/07/2015	30/07/2015	17/07/2017	25/10/2018
Vesting period (year)	exercisable as of subscription to the warrants	exercisable as of subscription to the warrants	exercisable as of subscription to the warrants	exercisable as of subscription to the warrants	4	4	4	3
Plan expiry date	09/09/2021	18/09/2021	08/09/2021	05/06/2024	02/07/2025	30/07/2025	17/07/2027	25/10/2028
Number of BSA allocated	8,000	2,000	4,100	2,000	28,284	32,683	22,500	75,600
Exercise price (€)	7.33	7.33	7.33	8.07	8.07	11.00	11.00	14
Valuation method used	Black and Scholes							
Underlying price (€)	7.33	7.33	7.33	8.09	7.76	7.76	11.20	7.54
Expected volatility	45.24%	53.42%	50.99%	49.11%	47.77%	48.39%	53.72%	45.90%
Discount rate	2.53%	2.26%	2.12%	1.83%	1.31%	0.94%	0.79%	0.77%
Fair value of the option (€)	3.12	3.52	3.38	3.59	3.21	2.52	5.24	2.18

Founders' stock options (BSPCEs)

	BSPCE 0313	BSPCE 0614	BSPCE 0615	BSPCE 0715	BSPCE 0915	BSPCE 0616	BSPCE 0616
Date of allocation (Management Board or General Meeting)	08/03/2013	05/06/2014	01/06/2015	30/07/2015	30/09/2015	13/06/2016	22/06/2016
Vesting period (year)	3	4	4	4	4	1	4
Plan expiry date	08/03/2018	05/06/2024	01/06/2025	30/07/2025	30/09/2025	13/06/2026	22/06/2026
Number of BSPCE allocated	53,500	123,773	15,000	190,000	38,000	75,000	119,500
Exercise price (€)	7.33	8.07	8.07	11.00	11.00	11.00	11.00
Valuation method Used	Black and Scholes						
Underlying price (€)	7.33	8.09	7.76	7.76	7.76	7.33	4.63
Expected volatility	50.99%	49.11%	47.18%	48.39%	49.53%	49.78%	49.78%
Discount rate	2.12%	1.83%	0.85%	0.94%	0.90%	0.41%	0.42%
Fair value of the option (€)	2.43	3.59	3.13	2.52	2.59	2.30	0.93

Stock options (OSAs)

Plan name	Stock options ⁰⁷¹⁷	Stock options ⁰⁵¹⁸	Stock options ⁰⁶¹⁸
Date of allocation (Management Board or Board of Directors)	17/07/2017	30/05/2018	13/06/2018
Vesting period (year)	4	May be exercised from the IPO	4
Plan expiry date	17/07/2027	30/05/2028	13/06/2023
Number of stock options allocated	28,000	36,270	5,000
Exercise price (€)	11.00	14.00	14.00
Valuation method used	Black and Scholes	Black and Scholes	Black and Scholes
Underlying price (€)	11.20	14	12.21
Expected volatility	53.72%	48.86%	47.09%
Discount rate	0.79%	0.71%	0.84%
Fair value of the option (€)	5.24	5.96	3.06

Allocation of free shares

Plan name	AGA ⁰⁴¹⁸
Date of allocation Board of Directors	11/04/2018
Vesting period (year)	1
Lock-up period	1
Number of shares allocated	25,415
Subscription price (€)	0.00
Valuation method used	Black and Scholes
Underlying price (€)	14.00
Expected volatility	48.76%
Discount rate	0.74%
Fair value of the free share (€)	14,00

At 31 December 2018, the total expense recognised in relation to incentive plans for executives and employees (BSPCE, BSA, Options and AGA) amounted to €613 k compared to €351 k for the year ended 31 December 2017.

4.5 Depreciation, amortisation

	Years ended December 31	
	2018	2017
Depreciation charge - assets	<1,828>	<1,522>
Total net depreciation	<1,828 >	<1,522>
Provisions against current assets		
Provisions for liabilities and expenses		<77>
Pension provisions	<40>	<7>
Provision reversals - liabilities and expenses	41	56
Reversals of provisions on other current assets		-
Total net provisions	1	<28>

Total net reversals

<1,827>

<1,550>

The amount of depreciation and amortisation linked to the capitalisation of development costs totalled €1,571 k for 2018 and €1,160 k for 2017.

4.6 Cost of net financial debt

The cost of net financial debt consists of loans and borrowings expenditures, in the amount of €568 k for 2018 and €588 k for 2017.

4.7 Income tax**4.7.1 [Tax expense](#)**

	Years ended December 31	
	2018	2017
Current income tax	3	22
Deferred tax		
Income tax	3	22

4.7.2 [Tax proof](#)

Reconciliation between the amount of income tax presented in the income statement and the theoretical income tax that would arise from the tax rate in force in France is analysed as follows:

In € thousands	Years ended December 31	
	2018	2017
Pre-tax income	<15,938>	<10,047>
Normal tax rate applicable in France (%)	28.00%	28.00%
(Expense) theoretical tax income	4,463	2,813
Impact of:		
- Differences in tax rates;	0	0
- Permanent differences;	<110>	<61>
- Allocation of profits w/o previous deficits;	52	37
- Adjustment for activation of deficits;	0	0
- Unused tax losses;	<4,282>	<3,151>
- Impact of consolidation adjustments;	<601>	343
- Other	3	<11>
- Tax credit.	478	0
(Expense) Tax income effectively recognised	3	22

Voluntis SA's unused tax losses for the 2018 financial year amounted to €15,291 k. At 31 December 2018, tax loss carryforwards totalled €56,377 k. These were not activated.

4.8 Net earnings per share

	Years ended December 31	
	2018	2017
Weighted number of shares in circulation	6,435,057	4,656,275
Weighted number of diluted shares	7,317,082	5,724,923
Basic earnings per share ⁽¹⁾ (in €)	(2.48)	(2.15)

⁽¹⁾ At 31 December 2018, instruments giving deferred access to capital are considered anti-dilutive since the Group recorded a loss for the year. Therefore, diluted earnings per share is identical to basic earnings per share.

NOTE 5 : NOTES TO THE CONSOLIDATED STATEMENT OF FINANCIAL POSITION

5

5.1 Intangible assets

Acquisitions of intangible assets corresponds primarily to the capitalisation of development costs incurred to develop digital solutions in the field of diabetes and oncology, as well as for the technological platform, meeting the activation criteria. Costs are adjusted by the corresponding research tax credit.

In € thousands	January 1, 2018	Acquisition /Increase	Disposals	Reclassification	31 December 2018
Patents and licences	273				273
Development costs	4,716	564	<1,675>	612	4,216
Other intangible assets	612	422		<612>	422
Gross values	5,600	986	<1,675>	0	4,911
Patents and licences	<268>				<268>
Development costs	<2,843>	<1,571>	1,672		<2,742>
Other intangible assets					
Depreciation	<3,111>	<1,571>	1,672		<3,010>
Patents and licences	5				5
Development costs	1,873			1,176	1,475
Other intangible assets	612			<1,176>	422
Net values	2,489	-	-	0	1,901

In € thousands	January 1, 2017	Acquisition /Increase	Disposals	Reclassification	31 December 2017
Patents and licences	273				273
Development costs	4,026	606		84	4,716
Other intangible assets	305	391		<84>	612
Gross values	4,604	997			5,600
Patents and licences	<245>	<24>			<268>
Development costs	<1,683>	<1,160>			<2,843>
Other intangible assets					
Depreciation	<1,927>	<1,184>			<3,111>
Patents and licences	29				5
Development costs	2,343			84	1,873
Other intangible assets	305			<84>	612
Net values	2,676	-	-	0	2,489

Some capitalised (software) development costs, amounting to €1,675 k, fully amortised and replaced in solutions by another version, were removed from intangible assets.

5.2 Tangible assets

Acquisitions primarily correspond to fixtures, constructions and computer equipment and hardware. The relocation of the primary establishment in Suresnes to new premises in 2017, requiring non-recurring investment costs, explains the return of tangible assets to a much lower level in 2018.

In € thousands	January 1, 2018	Additions	Disposals	Currency translation	31 December 2018
Property, plant and equipment	1,426	55	<215>	2	1,268
Other tangible assets	-	-	-	-	-
Gross values	1,426	55	<215>	1	1,268
Property, plant and equipment	<662>	<257>	215	<1>	<706>
Other tangible assets	-	-	-	-	-
Depreciation	(662)	<257>	215	-	<706>
Property, plant and equipment	764			1	563
Other tangible assets	-			-	-
Net values	764	-	-	1	563

In € thousands	1 January 2017	Additions	Disposals	Currency translation	31 December 2017
Property, plant and equipment	986	772	<328>	<4>	1 426
Other tangible assets	-	-	-	-	-
Gross values	986	772	<328>	<4>	1 426
Property, plant and equipment	<709>	<338>	383	1	<662>
Other tangible assets	-	-	-	-	-
Depreciation	<709>	<338>	383	1	<662>
Property, plant and equipment	277			<2>	764
Other tangible assets	-			-	-
Net values	277			<2>	764

5.3 Non-current financial assets

Non-current financial assets mainly consist of security deposits paid to the lessor.

In € thousands	Years ended December 31	
	2018	2017
Deposits and guarantees	253	241
Other financial assets	253	241

5.4 Trade and other receivables

Trade and other receivables break down as follows:

In € thousands	Years ended December 31	
	2018	2017
Non-current contracts assets	1,016	
Other non-current assets	1,016	
Trade receivables	1,525	360
Provisions for impairment	<20>	<61>
Net trade receivables	1,505	299

In € thousands	Years ended December 31	
	2018	2017
Down payments		30
Social security and tax claims	511	432
Prepaid expenses	372	144
Other receivables	3,525	1,716
Current contracts assets	1,037	
Current assets	5,445	2,322

Assets from non-current contracts with customers represent the portion exceeding one year of the costs of executing contracts, spread out in accordance with IFRS 15 in the amount of €1,016 k. The portion under one year is recognised in current contracts assets for the sum of €1,037 k. The total cost of executing contracts activated at 31 December 2018 amounts to €2,053 k.

The research tax credit, which amounts to €3,473 k, is recognised in other receivables at 31 December 2018, which includes €1,714 k with respect to 2017 and €1,790 k with respect to 2018.

Trade receivables were impaired by €20 k at 31 December 2018, with a €41 k reversal over the period. At the end of the last two reporting periods, the ageing analysis is as follows:

	In € thousands	Not due	Due since			
			less than 30 days	30 to 60 days	60 to 90 days	more than 90 days
31 December 2018	1,505	1,165	83	203	-	54
31 December 2017	299	188	99	-	-	11

5.5 Cash

Detail of cash (in € thousands)	Note	Years ended December 31	
		2018	2017
Cash		19,783	1,845
Cash equivalents			
Cash and cash equivalents reported in consolidated statement of financial position		19,783	1,845
Bank borrowings and overdrafts			
Closing cash on the statement of cash flow		19,783	1,845

At 31 December 2018, cash held by the Group consisted of €19,545 k and USD 242 k

5.6 Share capital

The Company was listed on the Euronext regulated market in Paris on 29 May 2018, as part of a global offering to raise a gross amount of €30.1 million by means of a capital increase. A total of 2,150,000 shares were created, with a nominal value of €0.10 per share combined with a share premium of €13.90.

The convertible bonds₂₀₁₇ were converted into 615,577 shares with a nominal value of €0.10 combined with a share premium of €13.90.

At 31 December 2018, the total amount of shares was 7,575,661 fully subscribed and paid up shares with a nominal amount of €0.10. Share capital therefore amounts to €757,566.10

This number excludes share subscription warrants (BSAs), founders' stock options (BSPCEs), stock options (OSAs) and allocations of free shares (AGAs).

Share capital solely comprises ordinary shares.

In € thousands	Years ended December 31	
	2018	2017
Capital at the start of the year	480	423
Proceeds from capital increase	277	57
Buy-back or cancellation of treasury shares		
Balance at year-end	758	480

5.7 Provisions

Provisions are detailed below:

In € thousands	2017	Provisions	Unused reversals	Used reversals	Actuarial gains	2018
Provisions for employee benefits	141	42			24	207
Provisions for disputes	77					77
Total	218	42			24	284
<i>Current</i>	<i>77</i>					<i>77</i>
<i>Non-current</i>	<i>141</i>	<i>42</i>			<i>24</i>	<i>207</i>

In € thousands	2016	Provisions	Unused reversals	Used reversals	Actuarial gains	2017
Provisions for employee benefits	130	9			1	141
Provisions for disputes		77				77
Total	130	86			1	218
<i>Current</i>		<i>77</i>				<i>77</i>
<i>Non-current</i>	<i>130</i>	<i>9</i>			<i>1</i>	<i>141</i>

The main actuarial assumptions used to determine the provision for employee benefits are summarised in the table below:

	2018	2017
Taux d'actualisation	1,80%	1,70%
Taux de progression des salaires	2%	2%
Taux de charges sociales	50%	50%
Turn over	0%	20%

5.8 Interest-bearing loans

The breakdown and changes in interest-bearing loans and borrowings over the two reporting periods under review are presented below:

5.8.1 [Changes during the reporting periods](#)

In € thousands	2017	Increase	Repayment	Interest payment	Capitalised interest ⁽¹⁾	Conversion / reclassification	2018
Convertible bond loans	3 715	7 550	<420>		162	<7 620>	3 387
Bank loans	370		<212>			93	252
Other loans	170		<170>			0	0
Loans	4 255	7 550	<802>		162	<7 527>	3 639
Bank borrowings and overdrafts	0						0
Interest-bearing loans	4 255	7 550	<802>		162	<7 527>	3 639

(1) including recognition of financial expenses calculated in accordance with IAS 32 for €121 k

In € thousands	2016	Increase	Repayment	Interest payment	Capitalised interest ⁽²⁾	Conversion / reclassification	2017
Convertible bond loans	6,303	3,550			163	<6,302>	3,715
Bank loans	475		<170>		65		370
Other loans	224		<66>			13	170
Loans	7,002	3,550	<236>		229	<6,290>	4,255
Bank borrowings and overdrafts	6		<6>				0
Interest-bearing loans	7,008	3,550	<242>		229	<6,290>	4,255

(2) including recognition of financial expenses calculated in accordance with IAS 32 for €125 k

5.8.2 [Breakdown by due date](#)

In € thousands	2017	2018	Current 31/12/2018	Non-current between 1 and 5 years	Non-current more than 5 years
Convertible bond loans	3,715	3,388	1,305	2,083	
Bank loans	370	251	135	116	
Other loans	170	0	0		
Loans	4,255	3,639	1,440	2,199	
Cash current accounts	6	0			

Interest-bearing loans and borrowings	4,255	3,639	1,440	2,199
--	--------------	--------------	--------------	--------------

5.8.3 [Convertible bond loans](#)

On 30 June 2017, the Group had issued a convertible bond loan of a maximum amount of €7.1 million. Following the Company's listing on the Euronext regulated market on 30 May 2018, on 31 May 2018, the Board of Directors recorded the automatic conversion of all of the convertible bonds issued by the Company into ordinary shares and the corresponding capital increase. The 71 million convertible bonds 2017 were converted into 615,577 ordinary shares.

5.8.4 [“Venture loan” financing contract combined with the issue of share subscription warrants](#)

On 11 April 2018, the Board of Directors issued a convertible bond loan in the amount of €7 million, subscribed for by the Kreos Company with drawdown in tranches. The repayment period is 36 months, and the contractual interest rate is 11%.

Only tranche A was issued as at 30 June 2018 in the amount of €4 million. The loan is combined with the issue of 70,000 share subscription warrants (BSAs) which may be exercised in proportion to the drawdowns of the bond debt and allocated in the amount of €1 providing access to ordinary shares at an exercise price of €11 per share. No share subscription warrants (BSAs) had been exercised at 31 December 2018.

For accounting purposes, this contract was treated as a financing commitment giving rise to the issue of a bond with share subscription warrants attached (OBSA). This includes a "debt" component measured at amortised cost and an option component. The latter was recognised in debt at inception, given the variable conversion parity of the BSA. It was then reclassified in shareholders' equity at 30 May 2018, date on which the conversion parity of instruments became fixed. The change in fair value between the initial accounting date and 30 May was recognised in financial income.

The debt relating to the loan breaks down as follows:

In € thousands	1 May 2018	31 May 2018	31 December 2018
Bond debt	3,783	3,547	3,486
Derivative component	217	216	
Shareholders' equity component			216
Total loan	4,000	3,763	3,388

5.8.5 [Interest free loan:](#)

On 24 June 2014, the Group was granted an interest free loan for innovation in the amount of €850k with Bpifrance Financement. The funds were made available in full in one single drawdown. The term

of amortisation of the loan is five years, and the first repayment is due on 06/01/2016.

The term of the loan includes a grace period, followed by a straight-line amortisation period, with a first deadline, at the end of the term, paid on 31/12/2015.

To measure the fair value of this loan, the Group used a discount rate of 15%, deemed to be representative of the debt ratio accessible to the Company.

The difference between the discounted value at market rate (i.e. the capital ultimately paid back in the absence of interest flows, discounted at market rate) and the amount received in cash from the public body constitutes a subsidy, within the meaning of IAS 20. This difference is recognised as a subsidy and not as a decrease in expenses, to the extent that these were completely depreciated in the financial statements at the end of 2015.

During the 2018 and 2017 financial years, the Group respectively recognised an interest expense of €51 k and €65 k for this loan. At 31 December 2018 and 2017 respectively, the balance on the balance sheet was €351 k and €370 k.

5.9 Other non-current liabilities

Non-current liabilities exclusively comprise deferred income relating to customer contracts.

The application of IFRS 15 results in the recognition of additional deferred income in the amount of €4,230 k at the end of December 2018, broken down into €3,213 k in non-current liabilities and €1,017 k in current liabilities.

5.10 Current liabilities

Current liabilities break down as follows:

In € thousands	2018	2017
Current financial debts	1,440	4,003
Provisions	77	77
Accounts payable and related accounts	2,062	1,492
Advances and prepayments received/recognised	0	138
Social security debts	1,875	1,826
Tax debts	381	315
Deferred income	1,781	523
Other debts	19	
Other current liabilities	4,057	2,801
Current liabilities	7,636	8,373

The change in deferred income was mainly due to the current share of contract liabilities, amounting to €1,017 k, resulting from the application of IFRS 15 (see previous note).

5.11 Fair value of financial assets and liabilities

At 31/12/2018					
In € thousands	Book value	Fair value through profit or loss	Available-for-sale financial assets	Amortised cost	Fair value through OCI
Non-current financial assets	253			253	
Non-current financial assets	253	0	0	253	0
Trade receivables	1,505			1,505	
Current financial assets	91			91	
Cash	19,783	19,783			
Current financial assets	21,378	19,783		1,596	
Total financial assets	21,631	19,783	0	1,849	0
Non-current financial debts	2,199			2,199	
Other non-current liabilities	3,328			3,328	
Non-current financial liabilities	5,527	0	0	5,527	0
Current financial debts	1,440			1,440	
Accounts payable	2,062			2,062	
Current financial liabilities	3,502	0	0	3,502	
Total financial liabilities	9,029	0	0	9,029	0
At 31/12/2017					
In € thousands	Book value	Fair value through profit or loss	Available-for-sale financial assets	Amortised cost	Fair value through OCI
Non-current financial assets	241			241	
Non-current financial assets	241	0	0	241	0
Trade receivables	299			299	
Current financial assets				0	
Cash	1,845	1,845			
Current financial assets	2,144	1,845		299	
Total financial assets	2,385	1,845	0	540	0
Non-current financial debts	252				252
Other non-current liabilities	322				322
Non-current financial liabilities	574	0	0		574
Current financial debts	4,003				4,003
Accounts payable	1,492				1,492
Current financial liabilities	5,495	0	0		5,495
Total financial liabilities	6,068	0	0		6,068

NOTE 6 : APPLICATION OF IFRS 15 RECONCILIATION TABLE

Income statement

In € thousands	31 December 2018 IFRS 15	Restatement IFRS 15/IAS 18	31 December 2018 IAS 18	31 December 2017 IAS 18
Revenue	4,533	<20>	4,513	7,302
Other income	637		637	1,095
Total operating income	5,170	<20>	5,150	8,396
Staff costs	<12,245>	1,119	<11,126>	<10,423>
Other operating costs	<6,909>		<6,909>	<6,048>
Depreciation, amortisation and provisions	<1,827>		<1,827>	<1,550>
Other non-recurring operating income and expenses	300		300	0
Operating income	<15,511>	1,099	<14,412>	<9,625>
Financial income	<427>	0	<427>	<423>
Taxes	3	0	3	22
Net income	<15,935>	1,099	<14,836>	<10,026>

Consolidated statement of financial position

In € thousands	31 December 2018 IFRS 15	Restatement IFRS 15/IAS 18	31 December 2018 IAS 18	31 December 2017 IAS 18
Assets				
Net intangible assets	1,901		1,901	2,489
Net tangible assets	563		563	764
Other net assets	253		253	241
Non-current assets related to contracts	1,016	<1,016>		
Non-current assets	3,732	<1,016>	2,717	3,494
Trade and other receivables	1,505		1,505	299
Other current assets	5,445	<1,037>	4,408	2,322
Current financial assets	91		91	
Cash	19,783	-	19,783	1,845
Current assets	26,823	<1,037>	25,786	4,466
Total	30,555	<2,053>	28,503	7,960
Liabilities and shareholders' equity				
Shareholders' equity	17,301	2,176 ⁽¹⁾	19,477	<1,127>
Non-current financial debts	2,199		2,199	252
Non-current provisions and other non-current liabilities	3,419	<3,213>	207	463
Non-current liabilities	5,618	<3,213>	2,406	714
Current financial debts	1,517		1,517	4,003
Trade and other payables	6,119	<1,017>	5,102	4,370
Current liabilities	7,636	<1,017>	6,619	8,373

Total	30,555	<2,053>	28,503	7,960
--------------	---------------	----------------------	---------------	--------------

- (1) Including €1,099 k in income and €1,077 k in consolidated reserves (see changes in shareholders' equity)

Restatement of the simplified cash flow statement

In € thousands	31/12/2018 IFRS 15	Restatement IFRS 15/IAS 18	31/12/2018 IAS 18	31/12/2017 IAS 18
Operating activities				
Net income	<15,935>	1,099	<14,836>	<10,026>
Depreciation, amortisation and provisions	1,868		1,868	1,550
Elimination of items which have no impact on cash flow	<786>		<786>	751
Net change in operating working capital requirements	128	<1,099>	<971>	2,329
<i>Cash flow generated by operations</i>	<i><14,726></i>		<i><14,726></i>	<i><5,396></i>
Investing activity				
Proceeds/(purchase) from/(of) tangible and intangible assets	<1,041>		<1,041>	<1,769>
Acquisition and disposal of financial assets	<296>		<296>	<132>
Other current financial investments	-		-	
<i>Cash flow from investing activities</i>	<i><1,336></i>		<i><1,336></i>	<i><1,900>-</i>
FINANCING ACTIVITIES				
Proceeds from capital increase	27,675		27,675	25
Issues, repayment of borrowings and financial interest paid	6,319		6,319	3,314
<i>Cash flow from financing activities</i>	<i>33,993</i>	-	<i>33,993</i>	<i>3,339</i>
CHANGE IN CASH FLOW	17,931	-	17,931	<3,958>
Impact of exchange rate fluctuations	7		7	<21>
OPENING CASH BALANCE	1,845		1,845	5,824
CLOSING CASH BALANCE	19,783	-	19,783	1,845

NOTE 7 : MANAGEMENT AND MEASUREMENT OF FINANCIAL RISKS

The Voluntis Group could be exposed to different types of financial risks: market risks, credit risks and liquidity risks. Where necessary, the Group implements simple methods adapted to its size to limit the potentially negative impacts of these risks on its financial position.

The Group specifies that it does not subscribe to financial instruments for the purposes of speculation.

6

7

7.1 Interest rate risk

The Group is exposed to interest rate risk. The Group's main financial instruments comprise bank loans and overdrafts with banks and cash. The Group also holds financial assets and liabilities such as commercial debts and receivables generated by its activities.

7.2 Liquidity risk

The management of liquidity risk aims to ensure that the Group has sufficient financing facilities to fulfil its current and future commitments. Management closely monitors rolling forecasts of liquidity reserves and the Group's cash and cash equivalents based on expected cash flows.

On the closing date, taking into account the available cash and the Company's development plan, a financing round is planned for the first half of 2018.

7.3 Credit risk

Credit risk derives from the following elements: cash and cash equivalents, non-current financial assets, derivative financial instruments and exposure to customers' credit risk, in particular through overdue receivables and transactions completed.

If customers have been rated by an independent entity, this rating is used. In the absence of this rating, the credit risk control department measures their solvency by taking into account their financial position and history as well as other factors.

7.4 Exchange rate risk

The operating exchange rate risks on operating flows or of a financial nature not paid in the functioning currency of the entities are not significant with regard to transactions in a foreign currency other than the euro.

The Group is therefore mainly exposed to exchange rates linked to conversion, for the preparation of the consolidated financial statements, of financial statements in the currencies of the consolidated subsidiaries with a functional currency that is not the euro.

NOTE 8 : OTHER INFORMATION

8

8.1 Off-balance sheet commitments

Commitments given

A first demand guarantee was granted to the lessor of the principal establishment for the amount of €211 k. This guarantee is counter-guaranteed to the benefit of the issuing bank in the form of a cash bond totalling €104k.

To guarantee the Kreos Bonds, the Company granted Kreos a collateral pledge on some of its assets (including receivables, bank accounts, and intellectual property rights).

Commitments received

Kreos has committed to subscribe for bonds issued by the Company for an additional amount of €3 million (€1.5 million for each additional tranche), subject to certain conditions.

Reciprocal commitments

Non applicable

8.2 Commitments linked to operating leases

In € thousands	Operating lease
2019	796
2020	511
2021	513
2022	432
2022	425
2024 and beyond	1,382
Total future rent⁽¹⁾	4,059

- 1) Includes €3,508 k in minimum future rent payments for the Group's headquarters in Suresnes in France (over the remaining term of the lease) and €551 k in minimum future rent payments for the premises of the US subsidiary in Cambridge, near Boston, in the United States.

8.3 Headcount

The Group's consolidated average headcount (FTE) was as follows in 2018 and 2017:

	Years ended December 31	
	2018	2017
Engineers and managers	106	101
Employees and technicians	1	2
Workforce	107	103

The average 2018 headcount consisted of 90 employees in France and 17 in the United States.

8.4 Related party transactions

The Group's related parties are executives of the Group and major shareholders (see transactions with BPI in Note 5.8.3 and Compensation of executives in Note 7.5).

The interest-free innovation loan agreement signed with Bpifrance Financement in 2014 is considered to have been granted to the Company under normal conditions in terms of the standard criteria for this type of financing by Bpifrance Financement.

The Company did not sign any material transactions with related parties under abnormal market conditions.

8.5 Compensation of senior executives

The amount of gross compensation received by the Group's administrative and management bodies totalled €1,447 k and €778 k respectively for 2018 and 2017.

(in €)	Years ended December 31	
	2018	2017
Compensation and benefits	1,047	600
Share-based payments	400	178
Total compensation	1,447	778

Some of the increase in compensation was a result of the Company's shares being listed on the stock market. This portion, amounting to €413 k, related to the arrival of new Board members and the exceptional bonuses paid at that time.

8.6 Post-closing events

On 12 March 2019, the Company notified Kreos of its wish to exercise the option to drawdown the additional tranches provided for in the Venture Loan Agreement entered into with Kreos, which was signed on 13 April 2018, for a total of €3 million. The payment of this amount will entitle Kreos to exercise 30,000 additional BSAs.

The Company also received the sum of €1,685 k on 28 February 2019, corresponding to the repayment of the 2017 research tax credit, including late payment interest of €31 k.

20.2 Statutory Auditors' reports on the consolidated financial statements prepared according to IFRS, as adopted by the European Union for the financial year ended 31 December 2018.

RBB BUSINESS ADVISORS

ERNST & YOUNG et Autres

Voluntis

Exercice clos le 31 décembre 2018

Rapport des commissaires aux comptes sur les comptes consolidés

RBB BUSINESS ADVISORS
113 bis, rue de l'Université
75007 Paris
S.A. au capital de € 150.000
414 202 341 R.C.S. Paris

Commissaire aux Comptes
Membre de la compagnie
régionale de Paris

ERNST & YOUNG et Autres
Tour First
TSA 14444
92037 Paris-La Défense cedex
S.A.S. à capital variable
438 476 913 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

Voluntis

Exercice clos le 31 décembre 2018

Rapport des commissaires aux comptes sur les comptes consolidés

A l'Assemblée Générale de la société Voluntis,

Opinion

En exécution de la mission qui nous a été confiée par vos assemblées générales, nous avons effectué l'audit des comptes consolidés de la société Voluntis relatifs à l'exercice clos le 31 décembre 2018, tels qu'ils sont joints au présent rapport.

Nous certifions que les comptes consolidés sont, au regard du référentiel IFRS tel qu'adopté dans l'Union européenne, réguliers et sincères et donnent une image fidèle du résultat des opérations de l'exercice écoulé ainsi que de la situation financière et du patrimoine, à la fin de l'exercice, de l'ensemble constitué par les personnes et entités comprises dans la consolidation.

L'opinion formulée ci-dessus est cohérente avec le contenu de notre rapport au comité d'audit.

Fondement de l'opinion

■ Référentiel d'audit

Nous avons effectué notre audit selon les normes d'exercice professionnel applicables en France. Nous estimons que les éléments que nous avons collectés sont suffisants et appropriés pour fonder notre opinion.

Les responsabilités qui nous incombent en vertu de ces normes sont indiquées dans la partie « Responsabilités des commissaires aux comptes relatives à l'audit des comptes consolidés » du présent rapport.

■ Indépendance

Nous avons réalisé notre mission d'audit dans le respect des règles d'indépendance qui nous sont applicables, sur la période du 1er janvier 2018 à la date d'émission de notre rapport, et notamment nous n'avons pas fourni de services interdits par l'article 5, paragraphe 1, du règlement (UE) n° 537/2014 ou par le Code de déontologie de la profession de commissaire aux comptes.

Observation

Sans remettre en cause l'opinion exprimée ci-dessus, nous attirons votre attention sur le paragraphe « IFRS 15 – Produits provenant des contrats avec les clients » de la note 3.2.1 « Nouveaux textes adoptés par l'Union européenne et applicable au 1er janvier 2018 » de l'annexe aux comptes consolidés qui présente l'impact de l'application d'IFRS 15.

Justification des appréciations - Points clés de l'audit

En application des dispositions des articles L. 823-9 et R. 823-7 du Code de commerce relatives à la justification de nos appréciations, nous portons à votre connaissance les points clés de l'audit relatifs aux risques d'anomalies significatives qui, selon notre jugement professionnel, ont été les plus importants pour l'audit des comptes consolidés de l'exercice, ainsi que les réponses que nous avons apportées face à ces risques.

Les appréciations ainsi portées s'inscrivent dans le contexte de l'audit des comptes consolidés pris dans leur ensemble et de la formation de notre opinion exprimée ci-avant. Nous n'exprimons pas d'opinion sur des éléments de ces comptes consolidés pris isolément.

■ Reconnaissance du chiffre d'affaires issu des contrats de licences

Risque identifié	Notre réponse
Le paragraphe 3.15.1 « Reconnaissance du chiffre d'affaires » de l'annexe aux comptes consolidés présente les principes de comptabilisation du chiffre d'affaires tiré de contrats conclus avec des clients. Le chiffre d'affaires du groupe est notamment issu de l'octroi de licences pour l'utilisation des logiciels du groupe. Lorsque la licence est distincte des autres prestations faisant l'objet du contrat, le groupe détermine pour chaque contrat si la licence consiste à accorder : ▶ un droit d'accès à la propriété intellectuelle telle qu'elle existe tout au long de la période couverte par la licence – auquel cas le chiffre d'affaires est étalé sur la durée la plus courte entre la durée de la licence et la durée d'utilité estimée de la propriété intellectuelle faisant l'objet de la licence, ▶ ou un droit d'utilisation de la propriété intellectuelle telle qu'elle existe au début de la période au cours de laquelle le client pourra utiliser la licence et en retirer les avantages - auquel cas le chiffre d'affaires est comptabilisé immédiatement à cette date. Lorsque la licence n'est pas distincte d'une autre obligation de prestation, le groupe détermine si l'obligation de prestation incluant la licence est remplie progressivement ou à un moment précis. Dans certains cas, le groupe doit réaliser des développements spécifiques avant que la licence ne soit utilisable par le client. La facturation de ces développements est considérée dans ce cas comme un complément du chiffre d'affaires rattaché à la licence dont la comptabilisation est différée jusqu'au début de la	Nos procédures d'audit ont notamment consisté à prendre connaissance des éléments justifiant les jugements et hypothèses clés utilisés par la direction pour déterminer la comptabilisation des accords de licences. Nos travaux ont principalement consisté à : ▶ prendre connaissance du processus mis en place au sein du groupe pour recenser et analyser les contrats clients ; ▶ examiner, en intégrant dans notre équipe des personnes ayant une compétence particulière en normes comptables, les éléments préparés par la direction financière, telles que les analyses de contrats au regard d'IFRS 15 ; ▶ réaliser des tests par sondages afin de rapprocher les montants comptabilisés des éléments sous-jacents (informations contractuelles, avenants, factures, état d'avancement etc.) ; ▶ examiner le traitement comptable et l'information financière donnée en annexe des comptes au regard de ces éléments de fond et des principes comptables applicables ; ▶ vérifier les principales formules de calcul utilisées.

période d'utilisation de la licence. Aussi, le chiffre d'affaires et les coûts associés aux développements sont reconnus au même rythme et sur la même durée que le chiffre d'affaires lié à la licence.

La comptabilisation de ces contrats repose donc sur le jugement et les estimations et hypothèses de la direction portant notamment sur :

- ▶ la nature de la licence (droit d'accès ou droit d'utilisation) ;
- ▶ le caractère distinct ou non de la licence par rapport aux autres obligations de prestations faisant l'objet du contrat client ;
- ▶ le cas échéant, l'estimation de la durée d'utilité de la propriété intellectuelle faisant l'objet d'une licence conférant un droit d'accès à cette propriété intellectuelle, telle qu'elle existe tout au long de la période couverte par la licence.

Nous avons considéré que la reconnaissance du chiffre d'affaires issu des contrats de licences constitue un point clé de l'audit en raison de sa sensibilité aux jugements et hypothèses retenus et de son caractère significatif.

■ Frais de développement

Risque identifié	Notre réponse
Comme indiqué dans la note 3.6.1 « Recherche et développement » de l'annexe aux comptes consolidés, les frais de développement de logiciels sont comptabilisés en immobilisations dès lors que ces derniers répondent aux critères d'activation tels que définis par IAS 38. La valeur nette comptable des actifs incorporels relatifs aux frais de développement s'élève à M€ 1,9 dont M€ 0,4 d'immobilisations incorporelles en cours au 31 décembre 2018. Les logiciels créés sont amortis sur la durée d'utilité de l'actif. La durée d'utilité est estimée de manière individuelle pour chaque logiciel. La date de début d'amortissement est définie par la survenance de l'un des événements suivants : ▶ signature du D.O. (Design Output) pour les produits déjà commercialisés et justifiant des autorisations réglementaires pour la version considérée ; ▶ à partir de l'obtention de la première autorisation ; ▶ constatation du premier euro de chiffre d'affaires. Nous avons considéré que l'évaluation des actifs incorporels relatifs aux frais de développement est un point clé de l'audit en raison de leur importance significative dans les comptes consolidés du groupe et des hypothèses nécessaires pour déterminer leur caractère activable et amortissable.	Nos procédures d'audit ont notamment consisté à prendre connaissance de l'évaluation et des éléments justifiant les hypothèses clés utilisées par la direction en particulier dans la détermination des durées d'utilité et sur le respect des critères d'activation. Nous avons notamment effectué les travaux suivants : ▶ prise de connaissance du processus de contrôle interne de suivi des frais de développement par entretiens avec la direction financière et le département Recherche et Développement ; ▶ analyse de l'évolution des projets de développement ; ▶ réalisation de procédures analytiques afin d'apprécier la cohérence de l'évolution des montants comptabilisés, avec l'avancement des projets de développement dans leur ensemble et les heures engagées par projet ; ▶ réalisation de contrôles arithmétiques sur le fichier de suivi des frais de développement ; ▶ réalisation de tests par sondages afin de rapprocher les montants activés des pièces justificatives (D.O., autorisations réglementaires, contrats clients, business plans etc.).

Vérifications spécifiques

Nous avons également procédé, conformément aux normes d'exercice professionnel applicables en France, aux vérifications spécifiques prévues par les textes légaux et réglementaires des informations relatives au groupe, données dans le rapport de gestion du directoire.

Nous n'avons pas d'observation à formuler sur leur sincérité et leur concordance avec les comptes consolidés.

Informations résultant d'autres obligations légales et réglementaires

■ Désignation des commissaires aux comptes

Nous avons été nommés commissaires aux comptes de la société Voluntis par votre assemblée générale du 9 mai 2018 pour le cabinet RBB BUSINESS ADVISORS et du 25 juin 2008 pour le cabinet ERNST & YOUNG et Autres.

Au 31 décembre 2018, le cabinet RBB BUSINESS ADVISORS était dans la première année de sa mission sans interruption et le cabinet ERNST & YOUNG et Autres dans la onzième année (dont une année depuis que les titres de la société ont été admis aux négociations sur un marché réglementé).

Responsabilités de la direction et des personnes constituant le gouvernement d'entreprise relatives aux comptes consolidés

Il appartient à la direction d'établir des comptes consolidés présentant une image fidèle conformément au référentiel IFRS tel qu'adopté dans l'Union européenne ainsi que de mettre en place le contrôle interne qu'elle estime nécessaire à l'établissement de comptes consolidés ne comportant pas d'anomalies significatives, que celles-ci proviennent de fraudes ou résultent d'erreurs.

Lors de l'établissement des comptes consolidés, il incombe à la direction d'évaluer la capacité de la société à poursuivre son exploitation, de présenter dans ces comptes, le cas échéant, les informations nécessaires relatives à la continuité d'exploitation et d'appliquer la convention comptable de continuité d'exploitation, sauf s'il est prévu de liquider la société ou de cesser son activité.

Il incombe au comité d'audit de suivre le processus d'élaboration de l'information financière et de suivre l'efficacité des systèmes de contrôle interne et de gestion des risques, ainsi que le cas échéant de l'audit interne, en ce qui concerne les procédures relatives à l'élaboration et au traitement de l'information comptable et financière.

Les comptes consolidés ont été arrêtés par le conseil d'administration.

Responsabilités des commissaires aux comptes relatives à l'audit des comptes consolidés

■ Objectif et démarche d'audit

Il nous appartient d'établir un rapport sur les comptes consolidés. Notre objectif est d'obtenir l'assurance raisonnable que les comptes consolidés pris dans leur ensemble ne comportent pas d'anomalies significatives. L'assurance raisonnable correspond à un niveau élevé d'assurance, sans toutefois garantir qu'un audit réalisé conformément aux normes d'exercice professionnel permet de systématiquement détecter toute anomalie significative. Les anomalies peuvent provenir de fraudes ou résulter d'erreurs et sont considérées comme significatives lorsque l'on peut raisonnablement s'attendre à ce qu'elles puissent, prises individuellement ou en cumulé, influencer les décisions économiques que les utilisateurs des comptes prennent en se fondant sur ceux-ci.

Comme précisé par l'article L. 823-10-1 du Code de commerce, notre mission de certification des comptes ne consiste pas à garantir la viabilité ou la qualité de la gestion de votre société.

Dans le cadre d'un audit réalisé conformément aux normes d'exercice professionnel applicables en France, le commissaire aux comptes exerce son jugement professionnel tout au long de cet audit. En outre :

- il identifie et évalue les risques que les comptes consolidés comportent des anomalies significatives, que celles-ci proviennent de fraudes ou résultent d'erreurs, définit et met en œuvre des procédures d'audit face à ces risques, et recueille des éléments qu'il estime suffisants et appropriés pour fonder son opinion. Le risque de non-détection d'une anomalie significative provenant d'une fraude est plus élevé que celui d'une anomalie significative résultant d'une erreur, car la fraude peut impliquer la collusion, la falsification, les omissions volontaires, les fausses déclarations ou le contournement du contrôle interne ;
- il prend connaissance du contrôle interne pertinent pour l'audit afin de définir des procédures d'audit appropriées en la circonstance, et non dans le but d'exprimer une opinion sur l'efficacité du contrôle interne ;
- il apprécie le caractère approprié des méthodes comptables retenues et le caractère raisonnable des estimations comptables faites par la direction, ainsi que les informations les concernant fournies dans les comptes consolidés ;
- il apprécie le caractère approprié de l'application par la direction de la convention comptable de continuité d'exploitation et, selon les éléments collectés, l'existence ou non d'une incertitude significative liée à des événements ou à des circonstances susceptibles de mettre en cause la capacité de la société à poursuivre son exploitation. Cette appréciation s'appuie sur les éléments collectés jusqu'à la date de son rapport, étant toutefois rappelé que des circonstances ou événements ultérieurs pourraient mettre en cause la continuité d'exploitation. S'il conclut à l'existence d'une incertitude significative, il attire l'attention des lecteurs de son rapport sur les informations fournies dans les comptes consolidés au sujet de cette incertitude ou, si ces informations ne sont pas fournies ou ne sont pas pertinentes, il formule une certification avec réserve ou un refus de certifier ;
- il apprécie la présentation d'ensemble des comptes consolidés et évalue si les comptes consolidés reflètent les opérations et événements sous-jacents de manière à en donner une image fidèle ;
- concernant l'information financière des personnes ou entités comprises dans le périmètre de consolidation, il collecte des éléments qu'il estime suffisants et appropriés pour exprimer une opinion sur les comptes consolidés. Il est responsable de la direction, de la supervision et de la réalisation de l'audit des comptes consolidés ainsi que de l'opinion exprimée sur ces comptes.

■ Rapport au comité d'audit

Nous remettons au comité d'audit un rapport qui présente notamment l'étendue des travaux d'audit et le programme de travail mis en œuvre, ainsi que les conclusions découlant de nos travaux. Nous portons également à sa connaissance, le cas échéant, les faiblesses significatives du contrôle interne que nous avons identifiées pour ce qui concerne les procédures relatives à l'élaboration et au traitement de l'information comptable et financière.

Parmi les éléments communiqués dans le rapport au comité d'audit figurent les risques d'anomalies significatives, que nous jugeons avoir été les plus importants pour l'audit des comptes consolidés de l'exercice et qui constituent de ce fait les points clés de l'audit, qu'il nous appartient de décrire dans le présent rapport.

Nous fournissons également au comité d'audit la déclaration prévue par l'article 6 du règlement (UE) n° 537-2014 confirmant notre indépendance, au sens des règles applicables en France telles qu'elles sont fixées notamment par les articles L. 822-10 à L. 822-14 du Code de commerce et dans le Code de déontologie de la profession de commissaire aux comptes. Le cas échéant, nous nous entretenons avec le comité d'audit des risques pesant sur notre indépendance et des mesures de sauvegarde appliquées.

Paris et Paris-La Défense, le 21 mars 2019

Les Commissaires aux Comptes

Jean-Baptiste Bonnefoux

Franck Sebag

20.3 Dividend distribution policy

Since its creation, the Company has not distributed any dividend. Given its stage of development, it does not plan to initiate a dividend policy in the short term.

20.4 Judicial and arbitration proceedings

As of the date of this Registration Document, the Company is not aware of any governmental, judicial or arbitration procedure, which is pending or that threatens the Group, which is likely to have or has had major effects on the Group's financial position or profitability over the last 12 months.

20.5 Significant change in the financial or commercial position

With the exception of what is described in this Registration Document, there has not been, to be Company's knowledge, any significant change in the Group's financial or commercial position since 31 December 2018.

20.6 Results for the last five years

in euros (except share and headcount data)	2014	2015	2016	2017	2018
CAPITAL AT THE END OF THE YEAR					
Share capital	321,407	347,016	423,153	480,208	757,566
Number of existing ordinary shares (1)	121,700	129,966	129,966	129,966	7,575,661
Number of existing preference shares					
- with preferential liquidation rights	3,092,365	3,340,197	4,101,561	4,672,118	0
- preferred dividend (without voting rights)	0	0	0	0	0
Maximum number of future shares to be created					
By bond conversion	0	0	570,600	332,408	0
By exercising subscription rights	1,305,967	1,363,102	745,238	736,240	838,025
OPERATIONS AND PROFIT (LOSS) FOR THE YEAR					
Pre-tax income	2,697,596	2,548,414	10,575,040	7,257,584	4,486,859
Income before tax, employee profit sharing and depreciation, amortisation and provisions	(4,585,754)	(10,843,884)	(3,769,495)	(9,293,165)	(13,174,674)
Income tax	(632,275)	(1,285,998)	(1,670,272)	(1,714,827)	(1,790,454)
Employee profit sharing due for the year					
Income after tax, employee profit sharing and depreciation, amortisation and provisions	(4,927,364)	(10,144,464)	(1,881,360)	(9,458,256)	(13,899,076)
Income distributed					
EARNINGS PER SHARE					

in euros (except share and headcount data)	2014	2015	2016	2017	2018
Income after tax, employee profit sharing before depreciation, amortisation and provisions	-1.24	-2.75	-0.51	-1.58	-1.50
Income after tax, employee profit sharing and depreciation, amortisation and provisions	-1.53	-2.92	-0.44	-1.97	-1.83
Dividend paid out	0	0	0	0	0
STAFF					
Average employee headcount during the year	55	63	79	91	90
Payroll for the year	3,695,222	4,483,928	5,264,662	6,115,837	6,081,400
Amount of employee benefits paid during the year	1,677,061	2,058,605	2,452,614	2,855,038	2,990,010

21. ADDITIONAL INFORMATION

21.1 Share capital

21.1.1 [Amount of the share capital](#)

On the date of the Registration Document, the Company's share capital amounts to €757,566.10 divided into 7,575,661 ordinary shares each with a nominal value of €0.10, fully paid up.

21.1.2 [Non-equity securities](#)

On 13 April, 2018, the Company concluded a bond issue agreement (taking the form of a Venture Loan Agreement and a Bond Issue Agreement) with Kreos. This bond is divided into three tranches for respectively €4 million (Tranche A), €1.5 million (Tranche B) and €1.5 million (Tranche C). At the Company's request, all of these tranches, totalling €7 million, were subscribed to by Kreos. (for further details regarding the terms of these bonds, see Section 22.6 of the Registration Document).

21.1.3 [Acquisition by the Company of its own shares – Treasury shares and share buyback](#)

The Combined General Meeting of the Company of 11 April 2018 authorised the Board of Directors to implement, for an eighteen-month (18) period from the meeting, a share buyback programme regarding the Company shares pursuant to the provisions of Articles L. 225-209 et seq. of the French Commercial Code and the market practices admitted by the French Financial Markets Authority (AMF).

21.1.3.1 *Terms of the authorisation*

The principal terms of this authorisation are as follows:

- **maximum number of shares that can be purchased:** 10% of the total number of shares, it being specified that (i) if the shares are acquired with the aim of encouraging the liquidity of the Company's shares, the number of shares taken into account to calculate this limit will correspond to the number of shares purchased less the number of shares sold during the term of this authorisation and (ii) if the shares are acquired with a view to conserving them and subsequent transferring them as payment or in exchange as part of a merger, split or contribution, the number of shares acquired cannot exceed 5% of the total number of shares;
- **purpose of share buy-backs:**
 - to ensure the liquidity of the Company's shares as part of a liquidity contract agreed with an investment service provider, in accordance with a code of ethics recognised by the Financial Markets Authority,
 - to fulfil the obligations linked to stock options, free share or employee savings plans or any other share allocations to employees and executives of the Company or its affiliated companies,
 - to allocate shares upon the exercise of rights attached to securities giving access to capital,
 - to purchase shares for conservation and subsequent delivery in exchange or as payment under possible external growth transactions, in accordance with market practices allowed by the Financial Markets Authority, or
 - more generally, operate for any other purpose that is authorised by French law or any market practice which is allowed by the market authorities, it being specified that in such circumstances, the Company informs its shareholders by means of a press release;

- **maximum purchase price (excluding fees and commission): €42.**
- **maximum amount of funds that may be used for share buy-backs: €3,000,000**

The shares purchased may be cancelled.

On the date of the Registration Document, the share buyback programme had only been used under the liquidity agreement signed on 8 June 2018 with Oddo Corporate Finance – see below.

21.1.3.2 Liquidity agreement signed with Oddo Corporate Finance

The aforementioned liquidity agreement, signed for a period of 12 months and renewable [automatically, on an annual basis], is for Company shares listed in Compartment C of the Paris Euronext regulated market. €300,000 was allocated to the liquidity account when the agreement was signed.

At 31 December 2018, the assets held in the liquidity account set up under this agreement amounted to €90,647 and 23,028 Company shares, or 0.30% of its existing share capital.

21.1.3.3 Employee share awards

In the year ended on 31 December 2018, the Company did not buy back any of its own shares with a view to awarding them to employees as part of a stock option, free share or employee savings plan or making any other share allocations to employees and executives of the Company or its affiliated companies.

21.1.3.4 Overview of share buyback transactions

The share buyback programme authorised by the General Meeting of shareholders on 11 April 2018 was only used as part of the liquidity agreement signed on 8 June 2018 with Oddo Corporate Finance.

The overview of share buyback transactions between 31 December 2018 and 28 February 2019 is as follows:

	From 31 December 2018 to 28 February 2019
Number of shares purchased	5,373
Average price	5.18
Volume traded upon purchase	27,817
Number of shares sold	5,341
Average price	5.21
Volume traded upon sale	27,839

	Position at 28 February 2019
Number of shares held	23,060
Carrying value of portfolio	178,891
Market value of portfolio	127,291

Treasury shares are recognised in other non-current financial assets in the annual financial statements and offset in the consolidated financial statements by a contra entry under equity.

21.1.4 [Financial assets giving access to capital](#)

On the date of the Registration Document, the financial instruments that are valid and give access to a share of the capital are of four different types (founders' stock options, warrants, stock options and free share awards).

Details of these dilutive instruments are given below.

21.1.4.1 Warrants for subscription to business creator shares (BSPCE)

The principal characteristics of the founders' stock options (the "BSPCE") issued by the Company are described in the table below:

	BSPCE ₂₀₁₄				BSPCE ₂₀₁₆₋₀₆	BSPCE ₂₀₁₆
Date of General Meeting	4 April 2014				13 June 2016	
Date of the Management Board's decision to allocate BSPCE	5 June 2014	1 June 2015	30 July 2015	30 September 2015	-	22 June 2016
Maximum number of BSPCE authorised	545,415				-	128,500
Total number of BSPCE allocated	132,671	15,000	206,000	38,000	75,000	128,500
Total number of shares to which the BSPCE are likely to give access on the date of their allocation	132,671	15,000	206,000	38,000	75,000	128,500
<i>Total number of shares that may be subscribed by the Company's corporate officers</i>	93,426	0	120,000	0	58,500	29,000
<i>Corporate officers concerned:</i>						
- <i>Pierre Leurent⁽¹⁾</i>	35,591	-	45,000	-	42,000	11,000
- <i>Romain Marmot⁽²⁾</i>	31,142	-	40,000	-	16,500	9,000
- <i>Alexandre Capet⁽³⁾</i>	26,693	-	35,000	-	-	9,000
Number of beneficiaries that are not corporate officers	4	2	5	7	1	25
Starting date to exercise BSPCE	5 June 2015	(7)	(8)	30 September 2016	13 June 2017	22 June 2017
Expiry date for BSPCE	5 June 2024 (4)	1 June 2025 (4)	30 July 2025 (4)	30 September 2025 (4)	13 June 2026 (4)	22 June 2026 (4)
Share subscription price on exercising BSPCE	8.07 €	8.07 €	€11	€11	€11	€11
Exercise method	(5)	(6)	(7)	(8)	(9)	(10)
Number of shares subscribed as of date of the Registration Document	0	0	0	0	0	0
Cumulative number of BSPCE expired or cancelled on the date of the Registration Document	8,898	0	16,000	15,000	0	24,000
Outstanding BSPCE on the date of the Registration Document	123,773	15,000	190,000	23,000	75,000	104,500

	BSPCE ₂₀₁₄				BSPCE ₂₀₁₆₋₀₆	BSPCE ₂₀₁₆
Total number of shares that may be subscribed on the date of the Registration Document (taking into account the conditions for exercising BSPCE)	123,773	15,000	174,514	17,250	75,000	52,250
Total maximum number of shares that may be subscribed on exercising all of the BSPCE outstanding on the date of the Registration Document (provided that the conditions for exercising said BSPCE are fulfilled) for the requirements of the table included in Section 18.1: 531,273	123,773	15,000	190,000	23,000	75,000	104,500

- (1) Until 11 April 2018, Pierre Leurent was Chairman of the Management Board of the Company in its form as a French société anonyme with a management board and a supervisory board. Following the transformation of the Company into a French société anonyme with a Board of Directors by the Combined General Meeting of 11 April 2018, he was appointed as a director and Chief Executive Officer of the Company.
- (2) Until 11 April 2018, Romain Marmot was a member of the Management Board and Chief Executive Officer of the Company in its form as a French société anonyme with a management board and a supervisory board. Following the transformation of the Company into a French société anonyme with a Board of Directors by the Combined General Meeting of 11 April 2018, he was appointed Deputy Chief Executive Officer of the Company.
- (3) Until 11 April 2018, Alexandre Capet was a member of the Management Board of the Company under its form as a French société anonyme with a management board and a supervisory board. Following the transformation of the Company into a French société anonyme with a Board of Directors by the Combined General Meeting of 11 April 2018, he was appointed Deputy Chief Executive Officer of the Company.
- (4) In any case, the BSPCE that can be exercised must be exercised, or risk expiry, (i) within the 3 months following the holder of the BSPCE ceasing all salaried functions or corporate offices within the Group, (ii) at the latest immediately prior to a merger or change in control of the Company to the benefit of a third-party, or (iii) within the 6 months after the holder of the BSPCE becomes incapacitated or deceased.
- (5) All the BSPCE allocated on 5 June 2014 were exercisable on the date of the Registration Document.
- (6) All the BSPCE allocated on 1 June 2015 were exercisable by each of the beneficiaries on the date of the Registration Document.
- (7) The BSPCE allocated on 30 July 2015 are exercisable for each of the beneficiaries up to 25% of the BSPCE on expiry of each year counting from the date on which the employee started at the Company. As a result, on the date of the Registration Document, 174,514 BSPCE are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.
- (8) The BSPCE allocated on 30 September 2015 can be exercised by each of the beneficiaries according to the following schedule:
 - 25% of the BSPCE counting from the first anniversary date of their allocation, i.e. 30 September 2016;
 - 25% of the BSPCE counting from the second anniversary date of their allocation, i.e. 30 September 2017;

- 25% of the BSPCE counting from the third anniversary date of their allocation, i.e. 30 September 2018;
- the balance, i.e. 25% of the BSPCE counting from the fourth anniversary date of their allocation, i.e. 30 September 2019.

As a result, on the date of the Registration Document, 75% of BSPCE are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.

(9) The BSPCE₂₀₁₆₋₀₆ allocated on 13 June 2016 are all exercisable on the date of the Registration Document.

(10) The BSPCE allocated on 22 June 2016 can be exercised by each of the beneficiaries according to the following schedule:

- 25% of the BSPCE counting from the first anniversary date of their allocation, i.e. 22 June 2017;
- 25% of the BSPCE counting from the second anniversary date of their allocation, i.e. 22 June 2018;
- 25% of the BSPCE counting from the third anniversary date of their allocation, i.e. 22 June 2019;
- the balance, i.e. 25% of the BSPCE counting from the fourth anniversary date of their allocation, i.e. 22 June 2020.

As a result, on the date of the Registration Document, 50% of BSPCE are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.

21.1.4.2 Warrants (BSA)

The principal characteristics of the warrants (the “BSA”) issued by the Company that are valid (with the exception of the BSA2018-Kreos whose characteristics are outlined in Section 21.1.4.3 below) are included in the following table:

	BSA ₂₀₁₄		BSA ₂₀₁₇	BSA ₂₀₁₈
Date of shareholders meeting	4 April 2014		30 June 2017	11 April 2018
Date of the Management Board's decision to allocate the BSA	2 July 2015	30 July 2015	17 July 2017	25 October 2018
Maximum number of warrants authorised	545,415		100,000	150,000
Total number of warrants allocated	28,284	32,683	22,500	75,600
Total number of shares to which the warrants are likely to give access on the date of their allocation	28,284	32,683	22,500	75,600
<i>Total number of shares that may be subscribed by the Company's corporate officers</i>	<i>28,284</i>	<i>32,683</i>	<i>22,500</i>	<i>75,600</i>
<i>Corporate officers concerned:</i>				
- Eric Elliott ⁽¹⁾	28,284	20,483	6,700	-
- Nicolas Cartier ⁽²⁾	-	12,200	15,800	-
- Viviane Monges	-	-	-	25,200
- Jan Berger	-	-	-	25,200
- Roberta Herman	-	-	-	25,200
Number of beneficiaries that are not corporate officers	0	0	0	0
Starting date to exercise warrants	28 December 2015	(6)	17 July 2017	25 October 2019
Expiry date for warrants	2 July 2025 (3)	30 July 2025 (3)	17 July 2027 (3)	25 October 2028 (10)
Issue prices of the BSA	€0.81	€1.10	€1.10	€2.30
Share subscription price on exercising warrants	€8.07	€11	€11	€14
Exercise method	(4)	(5)	(6)	(8)
Number of shares subscribed as of date of the Registration Document	0	0	0	0
Cumulative number of warrants expired or cancelled on the date of the Registration Document	0	0	0	0
Outstanding BSA as of the date of the Registration Document	28,284	32,683	22,500	75,600
Total number of shares that may be subscribed on the date of the Registration Document (taking into account the conditions for exercising warrants)	21,213	27,562	5,625	0
Total maximum number of shares that may be subscribed on exercising all of the warrants outstanding on the date of the Registration Document (provided that the conditions for exercising said warrants are fulfilled) for the requirements of the table included in Section 18.1: 159,067	28,284	32,683	22,500	75,600

- (1) Until 11 April 2018, Eric Elliott was Chairman of the Supervisory Board of the Company in its form as a French société anonyme with a management board and a supervisory board. Following the transformation of the Company into a French société anonyme with a Board of Directors by the Combined General Meeting of 11 April 2018, he was appointed Chairman of the Company's Board of Directors.
- (2) Until 11 April 2018, Nicolas Cartier was a member of the Board of Directors of the Company in its form as a French société anonyme with a management board and a supervisory board. Following the transformation of the Company into a French société anonyme with a Board of Directors by the Combined General Meeting of 11 April 2018, he was appointed a Company director.
- (3) In any case, the warrants that can be exercised must be exercised, or risk expiry, (i) within the 3 months following the holder of the warrants ceasing all salaried functions or corporate offices within the Group, (ii) at the latest immediately prior to a merger or change in control of the Company to the benefit of a third-party, or (iii) within the 6 months after the holder of the warrants becomes incapacitated or deceased.
- (4) Warrants allocated on 2 July 2015 can be exercised by each of the beneficiaries according to the following schedule:
 - 25% of the warrants counting from the first anniversary date of their allocation, i.e. 2 July 2016;
 - 25% of the warrants counting from the second anniversary date of their allocation, i.e. 2 July 2017;
 - 25% of the warrants counting from the third anniversary date of their allocation, i.e. 2 July 2018;
 - 25% of the warrants counting from the fourth anniversary date of their allocation, i.e. 2 July 2019.

As a result, on the date of the Registration Document, 75% of BSA are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.

- (5) The warrants allocated to Nicolas Cartier on 30 July 2015 are all exercisable on the date of the Registration Document.

The warrants allocated to Eric Elliott on 30 July 2015 are exercisable up to 25% of the warrants on expiry of each year ended counting from 12 June 2015. As a result, on the date of the Registration Document, 50% of BSA are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.

The warrants allocated on 17 July 2017 are exercisable at up to 25% of the warrants on expiry of each year ended counting from 17 July 2017. As a result, on the date of the Registration Document, 25% of the warrants are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party.

- (7) In any case, the warrants that can be exercised must be exercised, or risk expiry, (i) at the latest immediately prior to a merger or change in control of the Company to the benefit of a third-party, or (ii) within the 6 months after the holder of the warrants becomes incapacitated or deceases.
- (8) The warrants allocated on 25 October 2018 are exercisable up to one third (1/3) of the warrants on expiry of each year counting from 25 October 2018, provided that their holder has attended at least 75% of the Board meetings held in the last 12 months. As a result, on the date of the Registration Document, none of the warrants are exercisable, it being specified that they will all become exercisable in the event of a merger or change in control of the Company to the benefit of a third-party (in this event, the attendance condition is automatically lifted).

21.1.4.3 *BSA_{2018-Kreos}*

In exchange for a maximum bond loan of €7 million granted by Kreos to the Company, the Company allocated 70,000 share warrants to Kreos Capital V (Expert Fund) L.P. (the *BSA_{2018-Kreos}*). The main terms of the *BSA_{2018-Kreos}* will be as follows:

	BSA _{2018-Kreos}
Date of shareholders meeting	11 April 2018
Date of the Board of Directors meeting	
Maximum number of warrants authorised	70,000
Total number of warrants allocated	70,000
Total number of shares to which the warrants are likely to give access on the date of their allocation	(1)
Starting date to exercise warrants	(2)
Expiry date for warrants	(3)
Issue price of the warrant	€1 for all the BSA _{2018-Kreos} ⁽⁴⁾
Share subscription price on exercising warrants	(1)
Exercise method	(2)
Number of shares subscribed as of date of the Registration Document	0
Cumulative number of warrants expired or cancelled on the date of the Registration Document	0
Outstanding BSA as of the date of the Registration Document	70,000
Total number of shares that may be subscribed on the date of the Registration Document (taking into account the conditions for exercising warrants)	70,000 ⁽¹⁾
Total maximum number of shares that may be subscribed on exercising all of the warrants outstanding on the date of the Registration Document (provided that the conditions for exercising said warrants are fulfilled) for the requirements of the table included in Section 18.1: 70,000	70,000 ⁽¹⁾

(1) The BSA_{2018-Kreos} confer an entitlement to subscribe for 70,000 ordinary shares of the Company with a nominal value of €0.10 at a price per share of €11.

All of the BSA_{2018-Kreos} are exercisable as of the date of the Registration Document.

(3) The BSA_{2018-Kreos} will be automatically void as from the earliest of the following dates:

- 30 May 2023, and
- the date of completion of the disposal of all of the Company's shares.

(4) Kreos Capital V (Expert Fund) L.P. subscribed for all the BSA_{2018-Kreos} concurrently with the subscription by Kreos of the bonds issued by the Company on 11 April 2018 (see Section 22.7 of the Registration Document).

21.1.4.4 Stock options

The principal characteristics of the valid stock options (the “Options”) issued by the Company are included in the table below:

	Options ²⁰¹⁸	Options ²⁰¹⁸⁻²
Date of shareholders meeting	11 April 2018	11 April 2018
Date of the Management Board's or Board of Directors' decision to issue the Options	11 April 2018	13 June 2018
Maximum number of Options authorised	350,000	350,000
Total number of Options granted	36,270	5,000
Total number of shares to which the Options are likely to give access on the date of their allocation	36,270	5,000
<i>Total number of shares that may be subscribed by the Company's corporate officers</i>	<i>36,270</i>	<i>0</i>
<i>Corporate officers concerned:</i>		
- <i>Pierre Leurent</i>	<i>23,405</i>	-
- <i>Romain Marmot</i>	<i>12,865</i>	-
Number of beneficiaries that are not corporate officers	0	1
Starting date to exercise Options	11 April 2018	13 June 2019 (3)
Expiry date for Options	11 April 2028 (1)	13 June 2028 (1)
Share subscription price on exercising Options	€14	€14
Exercise method	(2)	(3)
Number of shares subscribed as of date of the Registration Document	0	0
Cumulative number of Options expired or cancelled on the date of the Registration Document	0	0
Outstanding Options on the date of the Registration Document	36,270	5,000
Total number of shares that may be subscribed on the date of the Registration Document (taking into account the conditions for exercising the Options)	36,270	0
Total maximum number of shares that may be subscribed by exercising all of the Options outstanding on the date of the Registration Document (providing that the conditions for exercising said Options have been fulfilled) for the requirements of the table included in Section 18.1: 41,270	36,270	5,000

- (1) In any case and unless otherwise decided by the Board of Directors, the Options may be exercised, or will otherwise become void, (i) within the three months following the holder of the Options ceasing all employee's functions or

corporate offices within the Group, (ii) at the latest immediately prior to a merger or change in control of the Company to the benefit of a third-party, or (iii) within the 6 months after the holder of the Options becomes incapacitated or deceases.

- (2) The Options₂₀₁₈ are all exercisable on the date of the Registration Document.
- (3) The Options₂₀₁₈₋₂ are exercisable at up to 25% of the Options from each year ended counting from the award date by the Board, i.e. as of 13 June 2019.

21.1.4.5 Free share allocations

The main characteristics of the allocations by the Company of free shares (the “Free Shares”) that are still valid are included in the following table:

	Free Shares ₂₀₁₈
Date of shareholders meeting	11 April 2018
Date of the decision of the Board of Directors allocating the Free Shares	11 April 2018
Maximum number of Free Shares that may be allocated	100,000
Total number of Free Shares allocated	25,415
<i>Total number of Free Shares allocated to corporate officers of the Company</i>	9,620
<i>Officers concerned</i> - <i>Alexandre Capet</i>	9,620
Number of beneficiaries that are not corporate officers	4
Number of Free Shares allocations in the course of being acquired	25,415
Acquisition date	11 April 2019
Methods of acquisition	(1)
End date of the retention period	11 April 2020
Number of Free Shares acquired on the date of the Registration Document	0
Cumulative number of AGA expired or cancelled on the date of the Registration Document	0
Outstanding Free Shares on the date of the Registration Document	25,415

- (1) The shares are vested at the end of a one year period.

21.1.4.6 Summary of dilutive instruments

On the date of the Registration Document, the total number of ordinary shares likely to be created by the full exercise of all of the rights giving access to the Company's capital, amounts to 827,025 shares, i.e. a maximum dilution of approximately 10.92% based on the capital existing on the date of the Registration Document and of approximately 9.84% on the basis of the diluted capital. Dilution of voting rights would be identical

21.1.5 Authorised capital

The table below summarises the different financial delegations of authority granted to the Board of Directors by the Combined General Meeting of shareholders of the Company on 11 April 2018:

	Term of validity/ Expiry	Limit (nominal value)	Methods for determining price	Dates and terms of use by the Board of Directors
Delegation of authority to be granted to the Board of Directors in order to increase the capital by issuing ordinary shares and/or any securities giving immediate or future access to the share capital, with preferential subscription rights (31 st resolution)	26 months	€385 k (1)	-	The Board did not use this delegation of authority during the past year
Delegation of authority granted to the Board of Directors in order to increase the capital by issuing ordinary shares or any securities giving immediate or future access to the share capital, with cancellation of preferential subscription rights of shareholders and public offering as well as with the option to create priority rights (32 nd resolution)	26 months	€385 k (1)	Please refer to (2)	The Board of Directors' meeting of 29 May 2018 used this delegation of authority to carry out a capital increase with a nominal value of €215 k by issuing 2,150,000 shares at a price of €14 each (including the issue premium)
Delegation of authority granted to the Board of Directors in order to increase the capital by issuing ordinary shares and/or any securities giving immediate or future access to the capital, with cancellation of preferential subscription rights in favour of qualified investors or a limited circle of investors referred to in Article L. 411-2 II of the French Financial and Monetary Code (33 rd resolution)	26 months	€385 k within the limit of 20% of the share capital per 12 month period	Please refer to (3)	The Board did not use this delegation of authority during the past year
Delegation of authority granted to the Board of Directors to increase the number of securities to be issued in the event of a capital increase with or without preferential rights performed under the above delegations (34 th resolution)	26 months	within the limit of 15% of the IPO (1) (4)	Same price as the IPO	The Board did not use this delegation of authority during the past year

	Term of validity/ Expiry	Limit (nominal value)	Methods for determining price	Dates and terms of use by the Board of Directors
Authorisation of the Board of Directors in the event of the issue of shares or any securities without preferential subscription rights for shareholders, to set the issue price (35 th resolution)	26 months	up to the limit of 10% of the share capital as existing on the date of the operation considered	Please refer to (5)	The Board did not use this delegation of authority during the past year
Delegation of authority granted to the Board of Directors to issue ordinary shares and securities giving access to the Company's share capital, in the event of a public offering initiated by the Company involving an exchange component (36 th resolution)	26 months	€48 k (1)		The Board did not use this delegation of authority during the past year
Delegation of power to the Board of Directors to issue ordinary shares or securities giving access to the capital of third-party companies outside the context of a takeover bid (37 th resolution)	26 months	€48 k up to the limit of 10% of share capital as existing on the date of the transaction considered		The Board did not use this delegation of authority during the past year
Delegation of authority to the Board for the purpose of increasing the share capital through the incorporation of premiums, reserves, profits or other items, the issue and allocation of free shares or by raising the par value of existing shares or by a combination of both these procedures (39 th resolution)	26 months	€1 million	-	The Board did not use this delegation of authority during the past year
Authorisation to be granted to the Board of Directors to grant stock options under the provisions of Articles L. 225-177 et seq. of the French Commercial Code. (41 st resolution)	38 months	350,000 shares (6)	Please refer to (7)	The Board meeting of 13 June 2018 used this delegation of authority to issue 5,000 options to a Group employee. Each option entitles the holder to subscribe for one share at a price of €14

	Term of validity/ Expiry	Limit (nominal value)	Methods for determining price	Dates and terms of use by the Board of Directors
Authorisation to be granted to the Board of Directors to allocate free shares, existing or to be issued, as part of the provisions of Articles L. 225-197-1 et seq. of the French Commercial Code. (42 nd resolution)	38 months	100,000 shares (6)	-	The Board did not use this delegation of authority during the past year
Delegation of authority for the Board of Directors to issue and allocate warrants to the benefit of (i) members and non-voting members of the Company's Board of Directors in office on the allocation date of said warrants and who are neither employees nor executives of the Company or one of its subsidiaries, (ii) persons connected to the Company under a service or consultancy contract, or (iii) members of any committee set up or that may be set up in future by the Board of Directors, who are neither employees nor executives of the Company or one of its subsidiaries (43 rd resolution)	18 months	150,000 shares (6)	Please refer to (8) and (9)	The Board of Directors' meeting of 25 October 2018 used this delegation of authority to issue 76,000 warrants, at a price of €2.30, to three independent directors. Each warrant entitles the holder to subscribe for one share at a price of €14
Authorisation of the Board of Directors in order for the Company to purchase its own shares(18 th resolution)	18 months	10% of the share capital	10% of the share capital	The Board bought back its own shares under the liquidity agreement signed on 8 June 2018 with Oddo Corporate Finance (see Section 21.1.3.2 of the Registration Document).
Authorisation to be granted to the Board of Directors in order to reduce the share capital by cancelling shares pursuant to the authorisation to buy back the Company's own shares (30 th resolution)	18 months	10% of the amount of share capital per period of 24 months	10% of the amount of share capital per period of 24 months	The Board did not use this authorisation during the past year

- (1) These amounts are not cumulative. The maximum ceiling authorised by the General Meeting for capital increases in nominal terms is fixed at €385,000. The global amount of issues of securities representing claims against the Company giving access to the Company's capital cannot, for its part, exceed €50,000,000. This limit does not apply to the debt securities if the issue has been decided or authorised by the Board of Directors in accordance with Article L. 228-40 of the French Commercial Code.
- (2) The issue price of shares will be at least equal to the weighted average price by volume during the last three preceding trading sessions, reduced, where appropriate by the discount authorised by law (i.e. currently 5%) and corrected in the event of differences in dividend eligibility dates, it being specified that the issue price of securities giving access to capital will be that of the sum immediately received by the Company, increased, where necessary, by that which may be subsequently received by the Company for each share issued as a result of the issue of these securities, at least equal to the issue price defined above;

- (3) The issue price of shares will be at least equal to the weighted average price by volume during the last three preceding trading sessions, reduced, where appropriate by the discount authorised by law, i.e. currently 5%, it being specified that the issue price of securities giving access to capital will be that of the sum immediately received by the Company, increased, where necessary, by that which may be subsequently received by the Company for each share issued as a result of the issue of these securities, at least equal to the issue price defined above;
- (4) 15% or any other part that may have been determined by the regulations in force;
- (5) Within the limit of 10% of the Company's capital (as it exists on the date of the transaction) per period of 12 months, to waive the conditions of price setting specified in the aforementioned resolutions and to fix the issue price of the ordinary shares and/or securities giving immediate or future access to the capital issued, according to the following methods:
- the issue price of ordinary shares will be at least equal to the weighted average by volume of listed prices on the three trading sessions prior to the price setting, possibly reduced by a maximum discount of 15%, under no circumstances can it be lower than the nominal value of a Company share on the issue date of the shares concerned,
 - the issue price of securities giving access to the capital will be the sum immediately received by the Company, increased, where appropriate, by that likely to be subsequently received by it, or, for each share issued as a result of the issue of these securities, at least equal to the issue price defined in the above paragraph;
- (6) These amounts are not cumulative; the maximum accumulated number authorised by the General Meeting likely to result from the exercise of stock options and warrants and the allocation of free shares is 350,000 shares;
- (7) the purchase or subscription price per share will be fixed by the Board of Directors on the day when the option is granted within the legal limits; this price cannot fall below ninety five per cent (95%) of the average price listed during the 20 trading days prior to the day of the Board's decision to allocate the options, rounded up to the nearest euro cent, nor in the case of purchase options, 80% of the average purchase price of treasury shares, rounded up to the nearest euro cent.
- (8) The issue price of a warrant will be determined by the Board on the date on which the warrants are allocated, based on the characteristics of the warrants and at least equal to 5% of the weighted average price by volume over the last three (3) trading sessions on said market or stock exchange preceding the allocation of said warrants by the Board.
- (9) The exercise price of a warrant will be set by the Board on the date of allocation and must be at least equal to the average of the prices listed on the 20 trading sessions prior to the decision of the Board of Directors to allocate the warrants.

21.1.6 Information on the capital of any member of the Group which is the subject of an option or of a conditional or unconditional agreement to put it under option

To the Company's knowledge, there is no option or conditional or unconditional agreement to implement such an option, on the Company's capital, with the exception (i) of the agreement signed between the Company's major shareholders on 4 April 2014, as modified by the amendments of 12 June 2015, 18 December 2015, 28 January 2016 and 11 April 2018, which will be cancelled on the date of settlement-delivery of the Company's shares on the regulated Euronext Paris market.

21.1.7 History of the share capital

21.1.7.1 Change in share capital

The Company was entered in the Trade and Companies Register on 5 November 2001, with capital of €40,000.

The share capital then increased on several occasions and reached, on 22 June 2016, €423,152.70 through the issue resulting from the exercise of warrants on 761,364 Category C preferred shares, with a nominal value of €0.10 each, at the price of €11 each (issue premium included), representing a cash contribution for a total amount of €8,375,0004 (issue premium included).

The table below presents a summarised form of the changes in capital since this date.

Date of transaction	Type of transaction	Number of shares issued or cancelled	Nominal amount (€)	Issue premiums or contributions (€)	Cumulative nominal amount of the share capital (€)	Cumulative total of outstanding shares	Nominal value (€)
3 April 2017	Capital increase by issuing preferred category C shares resulting from the conversion of convertible bonds	570,557	57,055.70	6,219,071.30	480,208.40	4,802,084	0.10
29 May 2018	Capital increase by issuing new ordinary shares	2,150,000	215,000.00	29,885,000	695,208.40	6,952,084	0.10
30 May 2018	Recognition of the capital increase through the issue of ordinary shares resulting from the automatic conversion of convertible bonds Conversion of all preferred shares issued by the Company into ordinary shares	615,577	61,557.70	8,556,520.30	756,766.10	7,567,661	0.10
31 August 2018	Recognition of the capital increase resulting from the exercise of warrants	8,000	800	57,840	757,566.10	7,575,661	0.10

21.1.7.2 Changes in the distribution of the Company's capital during the last two financial years

	Situation as of 31 December 2017		Situation as of 31 December 2018	
	Number of shares	% of share capital and voting rights ⁽¹⁾	Number of shares	% of share capital and voting rights ⁽¹⁾
Pierre Leurent*	213,400	4.44%	213,400	2.82%
Other	178,842	3.72%	206,149	2.72%
Total Management	392,242	8.17%	419,549	5.54%
CapDécisif Management ⁽²⁾	315,888	6.58%	1,567,582	20.69%
CM-CIC Innovation	734,809	15.30%	975,218	12.87%
SHAM Innovation Santé	879,926	18.32%	821,508	10.84%
Bpifrance Participations*	1,307,395	27.23%	609,839	8.05%
LBO France Gestion ^{(2)*}	523,122	10.89%	544,282	7.18%
Vesalius Biocapital II SA Sicar	457,600	9.53%	315,888	4.17%
Qualcomm Inc.	55,297	1.15%	55,297	0.73%

	Situation as of 31 December 2017		Situation as of 31 December 2018	
	Number of shares	% of share capital and voting rights ⁽¹⁾	Number of shares	% of share capital and voting rights ⁽¹⁾
Total - Financial investors	4,274,037	89.00%	4,889,614	64.54%
Other shareholders/consultants/employees holding registered shares	135,805	2.83%	116,498	1.54%
Free Float			2,150,000	28.38%
All other shareholders	135,805	2.83%	2,266,498	29.92%
TOTAL	4,802,084	100%	7,575,661	100%

* Member of the Company's Board of Directors

(1) The percentage of the voting rights is identical to the percentage of capital held.

(2) Through the Cap Decisif, Cap Decisif 2, and G1J funds of which it is the management company.

(3) Through the Services Innovants Santé et Autonomie (SISA) fund, of which it has been the management company since the acquisition of the management company Innovation Capital.

21.1.7.3 Distribution of capital and voting rights

See Section 18.1 of the Registration Document.

21.2 Memorandum and Articles of Association

The attached description takes into consideration certain amendments to the Articles of Association decided by the Combined General Meeting of shareholders on 11 April 2018.

21.2.1 Corporate purpose (Article 3 of the Articles of Association)

The purpose of the Company, in France and in all other countries is to:

design, publish and develop software, purchase, sell and lease software and in general all IT-related operations,

- research, assist, train, promote, provision of consultancy and other services to companies, in particular in relation to IT, office automation, robotics, multimedia and electronics, and for this purpose, the design, production, purchase, sub-contracting, sale, import, export of all related products and materials, as well as all related or ancillary activities;
- all of which directly or indirectly on its own behalf or on the behalf of others, either alone, or with a third-party, by means of creating new companies, contributions, sponsorships, purchase of securities or corporate rights, mergers, collaboration, joint venture or by obtaining the use of any property or rights under a lease, lease management agreement or by acceptance in lieu, or otherwise,

and generally, all financial, commercial, industrial transactions and transactions in movable property and real estate that may be directly or indirectly linked to the specified purposes or any similar or connected purpose or one that its likely to promote the development of the social capital.

21.2.2 Statutory regulations or other regulations relating to members of the administrative and management bodies

21.2.2.1 Board of Directors

The main provisions of the rules of procedure relating to the functioning of the Board of Directors are the subject of the developments presented in Section 16.3.1 of the Registration Document.

21.2.2.1.1 Composition of the Board of Directors (Article 11.1 of the Articles of Association)

The Company is administered by a Board of Directors composed of minimum three members and maximum twelve members.

Directors are appointed, renewed or revoked by the Ordinary General Meeting. They are always eligible for re-election.

Each legal entity must, at the time of their appointment, designate a natural person as a permanent representative to the Board of Directors. The term of office for the permanent representative is the same as that of the legal entity director that he or she represents. When the legal entity revokes its permanent representative, it must replace them as soon as possible. The same provisions apply in the case of the death or resignation of the permanent representative.

The term of office for directors is three (3) years. A director's term of office ends following the General Meeting of shareholders convened to vote on the financial statements for the year ended and held in the year during which the office of said director expires.

If one or several directors' seats become vacant due to death or resignation, the Board of Directors may, between two General Meetings, make temporary appointments.

Appointments made by the Board under the preceding point, are subject to the ratification of the next Ordinary General Meeting.

Failing ratification, the deliberations and acts carried out previously by the Board will nonetheless be valid.

If the number of directors falls below the legal minimum, the remaining directors must immediately convene an Ordinary General Meeting, with a view to making up the Board's members.

A Company employee may be appointed as a director only if their employment contract corresponds to active employment. In this case, the employee is still covered by their employment contract.

The number of directors linked to the Company by an employment contract cannot exceed one third of the directors currently in office.

The number of directors aged 70 or more cannot exceed one third of directors in office. If this limit is exceeded during a term of office, the oldest director is deemed to have automatically resigned at the end of the next General Meeting of Shareholders.

21.2.2.1.2 Chairmanship (Article 11.2 of the Articles of Association)

The Board of Directors elects from among its members a Chairman who must be a natural person. The Chairman determines the term of office, which cannot exceed their own office as director, and they may be revoked at any time. The Board sets the Chairman's compensation.

The Chairman organises and directs the Board's work and reports on this work to the General Meeting. They oversee the proper functioning of the Company and ensures in particular that the directors are able to fulfil their duties.

The Chairman of the Board must be aged 70 or younger. If the Chairman reaches this age while in office, he is deemed to have resigned from office. His term of office is extended until the next meeting of the Board of Directors during which his successor will be appointed. Notwithstanding this provision, the Chairman is always eligible for re-election.

21.2.2.1.3 Observers (Article 15 of the Articles of Association)

The Ordinary General Meeting may, on the proposal of the Board of Directors, appoint observers. The Board of Directors may also appoint these directly, subject to ratification by the next General Meeting.

The observer members form an advisory board. The number of observer members may not exceed five. Observer members are selected freely based on their competence.

They are appointed for a term of three (3) years ending following the General Meeting of shareholders convened to vote on the financial statements for the year ended and held in the year in which their term of office expires.

The observers study issues submitted by the Board of Directors or its Chairman for examination. The observers attend Board meetings and take part in deliberations in a consultative capacity only and their presence does not affect the validity of the deliberations.

They are convened to Board meetings under the same conditions as the directors. Their right to information and communications is the same as that of directors. They are subject to the same confidentiality obligations as directors.

The Board of Directors can compensate observers out of the attendance fees allocated to directors by the General Meeting.

21.2.2.1.4 Meeting of the Board of Directors (Article 12 of the Articles of Association)

The Board of Directors meets as often as required in the interests of the Company.

Directors are convened by the Chairman of the Board. They may be convened in writing.

The Chief Executive Officer may also request that the Chairman convene the Board of Directors on the basis of a predetermined agenda.

Moreover, at least one fourth of directors may request that the Chairman convene the Board on the basis of a predetermined agenda.

When a Works Council is established, the representatives of this council, appointed in accordance with the provisions of the French Employment Code, must be convened to all meetings of the Board of Directors.

The Chairman is bound by the requests submitted to him by virtue of the preceding two paragraphs.

Meetings of the Board take place either at the registered office or in any other location inside or outside France.

To ensure the validity of the Board's deliberations, the number of members present must be equal to at least half of the members.

Decisions of the Board of Directors will be taken by majority vote; in the event of a tie, the meeting's Chairman does not have the casting vote.

Rules of procedure to be adopted by the Board of Directors may provide that directors participating in the Board meeting by means of video-conferencing or telecommunications in accordance with the regulations in force will be deemed present for the calculation of quorum and majority. This provision does not apply to the adoption of the decisions outlined in Articles L. 232-1 and L. 233-16 of the French Commercial Code.

The President or CEO of the Company must communicate to each director the information required to fulfil its duties and mandate and as many documents as each director deems useful for this purpose.

Any director may assign authority to another director, by means of a letter, fax, e-mail or any other means of teletransmission, to represent them at a Board meeting. However, each director shall have, during the same session, only one single power of attorney.

Copies or extracts of the Board's deliberations are validly certified by the Chairman of the Board of Directors, the Chief Executive Officer, the director temporarily assigned to the functions of Chairman or a power of attorney duly authorised for this purpose.

21.2.2.1.5 Powers of the Board of Directors (Article 13 of the Articles of Association)

The Board of Directors determines the strategic orientation of the Company and oversees its implementation. Notwithstanding the power expressly allocated to the shareholders' meetings and within the limit of the corporate purpose, the Board handles all matters relating to the efficient running of the Company and regulates the Company's affairs through its deliberations.

With respect to relationships with third parties, the Company remains bound by the acts of the Board of Directors that are not within the Company's purpose, unless it can prove that the third-party knew that the act was outside the purposes or could not have been unaware of it in view of the circumstances; disclosure of the Articles of Association shall not of itself be sufficient proof thereof.

The Board of Directors performs the controls and checks that it deems necessary.

The Board of Directors also exercises the special powers granted to it by law.

21.2.2.2 General Management (Article 14 of the Articles of Association)

The general management of the Company is assumed, under its responsibility, either by the Chairman of the Board of Directors, or by a natural person appointed by the Board of Directors as the Chief Executive Officer.

The Chief Executive Officer is invested with the most extensive powers to act in all circumstances on behalf of the Company. It exercises these powers within the limits of the corporate purpose and subject to the powers expressly attributed to shareholders' meetings and the Board of Directors.

It represents the Company in its relations with third parties. The Company is also bound by the acts of its Chief Executive Officer which are outside the corporate purpose, unless it can prove that the third-party knew that the act was not in line with this purpose or could not have been unaware of it given the circumstances; disclosure of the Articles of Association shall itself be sufficient proof thereof.

The Chief Executive Officer must be 70 or younger. If the Chief Executive Officer reaches this age limit, he is deemed to have resigned from his office. His term of office will be extended until the next meeting of the Board of Directors during which the new Chief Executive Officer will be appointed.

When the Chief Executive Officer is also a director, the term of his functions cannot exceed his term of office as director.

The Board of Directors may revoke him at any time. If the revocation is without just cause, it may give rise to damages, except when the Chief Executive Officer is also the Chairman of the Board of Directors.

By simple deliberation taken by a majority of votes by the directors present or represented, the Board of Directors chooses between the two modes of general management outlined in the first part of this paragraph.

Shareholders and third parties are informed of this choice under the legal and regulatory conditions.

The Board of Directors' choice remains in effect until the Board decides otherwise or, at the Board's choice, for the term of office of the Chief Executive Officer.

If the general management of the Company is assumed by the Chairman of the Board of Directors, the provisions applicable to the Chief Executive Officer are applicable to him.

In accordance with the provisions of Article 706-43 of the French Code of Criminal Procedure, the Chief Executive Officer may legally grant power of attorney to any person of his choice to represent the Company in criminal proceedings that may be filed against it.

On the proposal of the Chief Executive Officer, the Board of Directors may grant a mandate to one or several natural persons to assist the Chief Executive Officer in his capacity as Deputy Chief Executive Officer.

In agreement with the Chief Executive Officer, the Board of Directors determines the extent and term of the powers granted to the Deputy Chief Executive Officers. The Board of Directors sets their compensation. If a Deputy Chief Executive Officer is also a director, the term of his functions cannot exceed his term of office as director.

With respect to third parties, the Deputy Chief Executive Officers have the same powers as the Chief Executive Officer; the Deputy Chief Executive Officers have in particular the power to act in legal proceedings.

The number of Deputy Chief Executive Officer cannot exceed five (5).

The Deputy Chief Executive Officer or Officers may be revoked at any time by the Board of Directors, on the proposal of the Chief Executive Officer. If the revocation is without just cause, it may result in damages.

A Deputy Chief Executive Officer must be 70 or younger. If a Deputy Chief Executive Officer reaches this age limit while in office, he is deemed to have resigned. His term of office will be extended until the next meeting of the Board of Directors during which a new Deputy Chief Executive Officer will be appointed.

When the Chief Executive Officer ceases or is prevented from exercising his duties, the Deputy Chief Executive Officer or Officers retain, unless otherwise decided by the Board of Directors, their functions and powers until the new Chief Executive Officer is appointed.

21.2.3 Rights, privileges, and restrictions on shares

21.2.3.1 Form of securities (Article 7 of the Articles of Association)

Fully paid up shares will be held in registered or bearer form, at the choice of each shareholder, subject to the application of legal provisions relating to the form of shares held by certain legal entities or natural persons. Shares that are not fully paid up will be held in registered form.

The shares are recorded in an account under the terms and conditions provided for under the legal and regulatory provisions in effect.

Ownership of shares held in registered form results from their registration in registered accounts.

21.2.3.2 Voting rights (Article 9 of the Articles of Association)

The voting right attached to shares is in proportion to the share of the capital that they represent and each share gives right to one vote.

Pursuant to Article L. 225-123 of the French Commercial Code, a double voting right is automatically applicable to all fully paid-up shares for which proof is provided of registration in the name of the same shareholder for at least two years.

The calculation of the holding period does not take into account the holding period for the Company shares prior to the listing of the Company shares on the regulated Euronext Paris market.

In accordance with Article L. 225-123 of the French Commercial Code, in the event of a capital increase through incorporation of reserves, profits or issue premiums, a double voting right is conferred, as of their issue, to shares registered by name and attributed free of charge to a shareholder as a result of old shares for which they were entitled to this right.

Any share converted to a bearer share or the ownership of which is transferred loses the double voting right granted in accordance with Article L. 225-123. However, transfer resulting from inheritance, the separation of assets between spouses or a living gift to a spouse or close relative does not result in the loss of rights acquired nor interrupt the qualifying period indicated above. This is also the case in the event of a transfer following a merger or split of a shareholder company.

The merger or split of the Company does not affect the double voting right that may be exercised within the beneficiary company or companies, if these exist.

The double voting rights in third-party companies held by the absorbed or split company are maintained, in the event of a merger or split, to the benefit of the absorbing company or the beneficiary company of the split, or, depending on the case, to the benefit of the new company resulting from the merger or split.

Any shareholder can, by recorded delivery with acknowledgement of receipt addressed to the Company, temporarily or definitively renounce all or part of their double voting rights. Said renunciation takes effect on the third working day following the Company's receipt of the renunciation letter.

21.2.3.3 Rights to dividends and profits (Article 9 of the Articles of Association)

Each share will give rise to the ownership of the company's assets, a share of the profits and liquidating rights, in proportion to the number and nominal value of existing shares.

21.2.3.4 Preferential subscription rights

The Company shares benefit from a preferential subscription right to capital increases under the conditions set out in the French Commercial Code.

21.2.3.5 Limitation of voting rights

There is no clause in the Articles of Association which restricts the voting rights attached to shares.

21.2.3.6 Identifiable bearer shares (Article 8 of the Articles of Association)

Insofar as the Company's shares are admitted to a regulated market, the latter may also, under the legal and regulatory conditions in force, request at any time, at its expense, from any duly authorised body the name, or, in the case of a legal entity, the company name, nationality, year of birth or year of constitution and the postal address and where applicable, e-mail address of the holders of securities granting immediate or future voting rights at its shareholders' meetings, as well as the number of shares held by each one and, where appropriate, the restrictions that may apply to these securities.

21.2.3.7 Purchase by the Company of its own shares

See Section 18.1 of the Registration Document.

21.2.4 Methods for changing shareholders' rights

Shareholders rights as presented in the Company's Articles of Association can only be modified by the Extraordinary General Meeting of the Company's shareholders.

21.2.5 General Meetings of Shareholders

21.2.5.1 Holding of meetings (Article 19 of the Articles of Association)

Collective shareholder decisions are taken at Ordinary, Extraordinary or Special General Meetings according to the nature of the decisions that they are convened to make. The Ordinary and Extraordinary General Meetings exercise their respective powers under the legal conditions in force.

General Meetings are convened and meet under the conditions, forms and deadlines set by law.

If the Company wishes to convene meetings by e-mail rather than postal letter, it must first of all obtain the approval of those shareholders interested who will provide their e-mail address.

Meetings take place at the registered office or any other location specified in the meeting notice.

Each shareholder, regardless of the number of shares they hold, may attend General Meetings and participate in deliberations, personally, by proxy or by remote voting, under the conditions and within the time periods provided by the regulations in force.

Shareholders may, under the conditions set by the regulations in force, send their postal voting form relating to any General Meeting, either in paper form or, on the decision of the Board of Directors, included in the meeting notice, by e-mail.

The Board of Directors may organise, under the legal and regulatory conditions in force, the attendance and voting of shareholders by video-conference or other means of telecommunication that ensures the identification of the attendees. If the Board of Directors decides to exercise this power for a given meeting, it must inform of this decision in the meeting notice. Shareholders participating in meetings by video-conference or the other means of telecommunication listed above, according to the choice of the Board of Directors, are deemed present for the calculation of quorum and majority.

The postal voting forms and the proxies granted to represent a shareholder at a meeting may include the electronic signature of the shareholder or their legal representative by means of a process that is compliant with the requirements of Article 1316-4 paragraph 2 of the French Civil Code, i.e. a reliable identification process guaranteeing the signature's connection with the instrument to which it is attached.

Each shareholder has the right to the documents required to allow them to vote with full knowledge of the issue with regards to the management and functioning of the Company.

The nature of these documents and the conditions of their dispatch and availability are determined by law and regulations.

Meetings are presided by the Chairman of the Board of Directors or, in his absence, the Chief Executive Officer, by a Deputy Chief Executive Officer if they are also a director, or by a director specially appointed by the Board for this purpose. Otherwise, the meeting elects its own Chairman.

The functions of tellers are performed by the shareholders present, and who accept these functions, who have, on their own and as representatives, the largest number of votes.

A secretary will be appointed, who can be chosen outside the shareholders.

An attendance sheet is kept under the legal conditions in force.

When first convened, the Ordinary General Meeting, may only deliberate validly if the shareholders present or represented hold at least one fifth of the shares with voting rights. When convened for the second time, the Ordinary General Meeting may deliberate validly regardless of the number of shareholders present or represented.

The deliberations of the Ordinary General Meeting are taken by the majority of votes of the shareholders present or represented.

When first convened, the Extraordinary General Meeting, may only deliberate validly if the shareholders present or represented hold at least one fourth of the shares with voting rights. When convened for the second time, the Extraordinary General Meeting, may only deliberate validly if the shareholders present or represented hold at least one fifth of the shares with voting rights.

The deliberations of the Extraordinary General Meeting are taken by the majority of votes of the shareholders present or represented.

When first convened, the Special General Meeting may only deliberate validly if the shareholders present or represented hold at least one third of the shares with voting rights. When convened for the second time, the Special General Meeting, may only deliberate validly if the shareholders present or represented hold at least one fifth of the shares with voting rights. The deliberations of the Special General Meeting are taken by the majority of votes of the shareholders present or represented.

Minutes are taken in accordance with the law. Copies or extracts of the meeting minutes are validly certified by the Chairman of the Board of Directors, by a director exercising the functions of Chief Executive Director or by the meeting secretary.

The Ordinary and Extraordinary General Meetings exercise their respective powers under the legal conditions in force.

21.2.5.2 Powers of the Meetings

The Ordinary and Extraordinary General Meetings exercise their respective powers under the legal conditions in force.

21.2.6 Provisions that may delay, defer or prevent a change in control

The Company's Articles of Association do not contain any bylaws that may delay, defer or prevent a change in control.

21.2.7 [Crossing of statutory thresholds](#)

Non applicable

21.2.8 [Special provisions governing changes in capital](#)

The Articles of Association do not contain any provisions governing changes to capital.

22. MATERIAL CONTRACTS

Except for the agreements described below, the Group has not entered into any material contracts other than those entered into in the normal course of its business.

22.1 Partnership agreement with AstraZeneca of 24 November 2015 (eCo Project)

The Company has entered into a collaboration and option agreement with AstraZeneca UK Limited (“AstraZeneca”) for a software device developed by the Company. The agreement is governed by English law and submits any dispute to arbitration.

22.1.1 [Purpose of the collaboration agreement](#)

Under the terms of this agreement, the Company is developing a software device (the “Device”) in accordance with specifications established by AstraZeneca. The Device is intended to be used to optimise the management and improve the tolerability of a therapy (the “Product”) composed of Cediranib (in Phase II/III of development by AstraZeneca) and Olaparib (marketed by AstraZeneca and Merck under the brand name LYNPARZA) (the “Compounds”), for the treatment of ovarian cancer (the “Field”).

For a period due to end once the clinical evaluation data cease to be available (the “Option Period”), the Company grants AstraZeneca an exclusive worldwide licence to use the Device solely for the purposes of research and development of the Compounds and of the Product in the Field, AstraZeneca being entitled to sub-licence the Device to any third-party.

During the ergonomic and clinical evaluation phase of the Device, the Company agrees to provide AstraZeneca with services such as hosting, maintenance, support and medical device vigilance.

22.1.2 [Financial consideration](#)

If the agreement is successful, AstraZeneca agrees to pay the Company, in consideration of the rights of use and distribution of the Device, different amounts that could potentially total a maximum of €7.8 million subject to following conditions being achieved:

- upon signing the partnership agreement, payment having already been made for this stage;
- during different phases of the design and development of the Device;
- upon reaching regulatory milestones; and
- on an annual basis regarding the costs associated with procedures carried out during the usability pilot phase and clinical evaluation phase of the Device.

Moreover, the parties undertake to negotiate in good faith the amount of royalties periodically due following the marketing of the Product.

22.1.3 [Intellectual property](#)

Each party retains ownership of the intellectual property rights protecting its technology and the improvements made in connection with this. It is also provided that, irrespective of the originating party:

- the intellectual property rights protecting the Compounds and/or the Product belong to AstraZeneca; and
- the intellectual property rights protecting the Device belong to the Company.

AstraZeneca is working with the US National Cancer Institute (NCI) on this project, via a cooperative research and development agreement (CRADA).

22.1.4 Term

The partnership agreement entered into force on 24 November 2015 for a term of five years.

22.1.5 Termination conditions

Either party may terminate the agreement in the event of (i) a material breach of the obligations of the other party, not remedied within 60 days of notification of the breach sent to that party by the first party, and (ii) suspension of payments of the other party, commencement of insolvency proceedings against it, an assignment for the benefit of creditors or the appointment of a trustee for all or a substantial portion of the assets of that other party.

In addition, AstraZeneca may terminate the agreement at any time, without explanation, subject to payment in full to the Company of the proportional amount due under the agreement (corresponding to the costs of procedures carried out prior to the marketing of the Device).

22.2 Partnership and licensing agreement with Sanofi France (Diabeo Project)

On 29 July 2011, the Company entered into a partnership agreement with Sanofi-Aventis France (“Sanofi France”) and the French research centre for diabetes treatment intensification (“CERITD”) concerning “Diabeo”, a medical software device that uses components of the technology platform developed by the Group (the “Diabeo Solution”). This partnership agreement has been amended several times. This agreement is governed by French law and any dispute is subject to the jurisdiction of the Paris Courts.

22.2.1 Purpose of the partnership agreement

The aim of the partnership agreement is to define the operational, commercial and legal conditions for the development, certification, registration, promotion and marketing of the Diabeo Solution between the parties.

Under the terms of this agreement, Sanofi France undertakes to assist in the scientific and technological development of the Diabeo Solution, particularly through studies and certification.

In return, the Company grants Sanofi France an exclusive right to market the Diabeo Solution in France. On that basis, the Company and CERITD agree not to develop for marketing purposes or to market in France a competing solution to the Diabeo Solution without the prior written consent of Sanofi France. Sanofi France is responsible for promoting the Diabeo Solution.

The Company also agrees to host the data relating to the Diabeo Solution and to ensure that its design and production meet the essential health and safety requirements. The Company is also required to obtain the necessary approvals for the CE marking of the Diabeo Solution and to register the solution with the French National Agency for Medicines and Health Products Safety (ANSM) as a medical device.

CERITD is responsible for the medical and scientific content of the Diabeo Solution.

The five amendments signed between July 29, 2013 and April 20, 2017 had the effect of adjusting the schedule for the completion of the development project and the clinical study and the billing schedule as it progressed, adjusting the governance of the project after the first three years, increasing the scope of specific development services and finally amending the exclusivity conditions and certain financial conditions, in order to link the Diabeo Collaboration contract with Insulia's distribution contracts.

22.2.2 Financial consideration

Sanofi France

Upon signing the partnership agreement and during the subsequent development and regulatory phases, Sanofi France paid various fixed amounts to the Company and CERITD, with the Company receiving a total of €6.95 million.

Furthermore, Sanofi France commits to pay the Company and CERITD, following the commercial launch of the Diabeo Solution:

- two milestone payments contingent on achieving the sales targets calculated over a period of 12 consecutive months; and
- quarterly royalties calculated on the basis of a percentage of the net revenue generated by the Diabeo Solution, this double-digit percentage varying according to the amount of revenue actually earned.

Lastly, Sanofi France is covering the cost of “Telesage”, a study aimed at proving the therapeutic efficacy of the Diabeo Solution.

Company

If the Diabeo Solution is marketed outside France, the Company agrees to pay Sanofi France royalties equal to a single-digit percentage of the net revenue earned by the Company (subject to a maximum set amount).

22.2.3 Intellectual property

The intellectual property rights on the Telesage study are jointly held by Sanofi France and CERITD worldwide; the Company also has a worldwide licence to exploit the results of this study.

The Company owns the software component of the Diabeo Solution and the modules from the technology platform, except for (i) the specific developments it co-owns with Sanofi France and (ii) the functional insulin therapy programme and the algorithmic component of the Diabeo Solution developed and owned by CERITD. The Company and CERITD have licensed the exploitation rights to the Diabeo Solution in France to Sanofi France.

The Diabeo Solution source codes must be filed with the French Software Protection Agency and Sanofi France may, in certain circumstances, have access to them, in particular, in the event that the Company terminates the partnership agreement at any time, of judicial liquidation or that the Company fails to meet its obligations. If Sanofi France accessed the source code of the Diabeo Solution on that basis, the Company would have to grant it a licence to use the Diabeo Solution, including, subject to the payment of royalties, the Medpassport platform for France.

Under the terms of the partnership agreement, ownership of the “Diabeo” trademark for certain countries and classes was assigned to Sanofi France. In return, Sanofi France granted the Company a right to use the trademark in the conditions stipulated in the partnership agreement. In the event of termination, and if Sanofi France does not want to continue to use the brand, the Company has a right of first refusal to acquire the trademark if it wishes to use the Diabeo Solution.

22.2.4 Term

The partnership agreement was entered into for an initial term due to expire on 31 December 2020. At the end of this initial term, the agreement will continue indefinitely.

[22.2.5 Termination conditions](#)

During the initial term, the partnership agreement may be terminated if one of the parties breaches its obligations, or if certain events or conditions occur, in particular if the intermediate results of the Telesage study are unsatisfactory.

In addition, at the end of the initial term, either party may decide to unilaterally terminate the partnership agreement subject to reasonable notice.

Lastly, each party may unilaterally terminate the agreement in the event of a force majeure event lasting more than two months.

In any event, the party that initiates the termination or the party at fault may not continue to develop or market the Diabeo Solution.

[22.2.6 Other contractual provisions](#)

Sanofi France must be informed of any proposed change in control of the Company. Sanofi France may decide at its discretion to (i) terminate the agreement or (ii) continue the performance of the agreement subject to certain major amendments if the change of control benefits specific competitors named in the agreement.

22.3 Non-exclusive licence and collaboration agreement with Sanofi (for the distribution of Insulia)

The Company has entered into a non-exclusive licence and collaboration agreement with Sanofi S.A. (“Sanofi”) for the distribution of two digital medical devices, one for patients with type 1 and 2 diabetes treated with basal and bolus insulin (the “ITA 1 Solution”) and the other for patients with type 2 diabetes treated with basal insulin (the “ITA 2 Solution” and, together with the ITA 1 Solution, the “ITA Solutions”). The agreement concerns the solution developed by the Company under the Insulia trademark on the basis of the Theraxium technology platform, both of which are owned exclusively by the Company. This agreement is governed by French law and any dispute is subject to the jurisdiction of the Paris Commercial Court.

[22.3.1 Purpose of the licensing and services agreement](#)

Under the terms of this agreement, the Company grants Sanofi a non-exclusive worldwide licence (except for France as regards the ITA 1 Solution) with the option of granting sub-licences to develop and market products and services including one of the ITA Solutions, and to use the development and hosting platform developed by the Company (the “Theraxium Technology”) to the extent necessary for the development and marketing of products and services including the ITA Solutions. The Company is also adapting the ITA Solutions to the titration of U300 insulin glargine owned and marketed by Sanofi under the brand name “Toujeo”.

In addition, the Company must provide Sanofi with access to anonymised end user data. The Company is also responsible for (i) obtaining all necessary approvals for the manufacture, promotion, import and sale of the ITA 2 Solution in all countries and (ii) notifying the regulatory authorities of any safety related event concerning the ITA 2 Solution.

Lastly, the Company undertakes to provide Sanofi with corrective maintenance, hosting, server availability, backup, management and technical support services (excluding technical support for end users).

22.3.2 Financial consideration

Prior to the commercial launch of any ITA Solution, Sanofi agrees to make various lump sum payments to the Company which could potentially reach a maximum of €5 million. It is specified that as of the date of this Registration Document, all such payments have already been made.

Following the commercial launch of any ITA Solution, Sanofi further agrees to pay the Company:

- monthly royalties calculated according to the number of active users each month for each of the ITA Solutions and their usage period of the ITA Solution concerned, the royalty varying by increments of active users and their place of residence;
- a performance bonus for each active user who achieves the treatment goals defined for a specified period.

22.3.3 Intellectual property

The Company and Sanofi each retain their respective intellectual property rights protecting the elements created before 23 March 2016 or created separately during the term of the agreement. As such, the Company owns the ITA Solutions and the Theraxium technology platform. The intellectual property rights to the items created jointly will be held in co-ownership. Sanofi grants the Company, for the term of the agreement, a non-transferable licence to utilise user data for the purposes of supplying, improving and assessing the performance of the ITA Solutions, as well as maintaining the related regulatory approvals.

The agreement provides the option for Sanofi to access the source codes of the ITA Solutions if the Company discontinues its activity in relation to the ITA Solutions and has no successor to take over all of the Company's obligations under this agreement.

22.3.4 Term

The partnership agreement entered into effect on 23 March 2016 and will remain in effect until terminated according to the conditions set out below.

22.3.5 Termination conditions

The agreement may be terminated by the Company in the event of (i) a force majeure event affecting Sanofi for a period of more than 90 days, (ii) a material breach of Sanofi's obligations, not remedied within 60 days of notification of the breach sent by the Company to Sanofi, and (iii) suspension of payments of Sanofi, commencement of insolvency proceedings against it, an assignment for the benefit of creditors or the appointment of a trustee for all or a substantial portion of Sanofi's assets or any other similar action.

Furthermore, Sanofi may terminate this agreement at any time.

22.4 Non-exclusive licence and services agreement with Verily

On 26 February 2016, the Company entered into a non-exclusive licensing and services agreement with Verily Life Sciences LLC ("Verily"). This agreement is governed by the law of the State of Delaware (United States), and any dispute is to be referred to the competent courts of the State of Delaware.

Verily has indicated to the Company that it intends to explore the use of Company technology in connection with its development of innovative treatments for patients with diabetes, mainly via Onduo, a joint venture Verily established with Sanofi in 2016. The Company has also entered into an additional agreement directly with Onduo (see Section 22.5 of the Registration Document).

22.4.1 Purpose of the licensing and services agreement

Under the terms of this agreement, the Company grants Verily a non-exclusive, non-transferable, worldwide licence excluding France, with the option of granting sub-licences, (i) to incorporate the ITA 1 and/or ITA 2 Solutions into the platform developed by Verily (the “Platform”), (ii) to market and distribute ITA Solution 1 and / or ITA Solution 2 under the Company’s brand names and / or under its own brand names, on its Platform or independently and (iii) to use the Theraxium technology platform to the extent necessary to incorporate the ITA Solutions into the Platform and to market the ITA Solutions.

The Company is responsible for (i) obtaining all necessary approvals for the manufacture, promotion, import and sale of the ITA Solutions in all countries (CE marking in the European Union and 510(k) clearance in the United States), and (ii) notification of the regulatory authorities of any safety-related event concerning the ITA Solutions.

Under the terms of this agreement, the Company undertakes to provide Verily with corrective maintenance, hosting, server availability, backup, management and technical support services (excluding technical support for end users).

Verily has the option of developing, obtaining a licence for, and/or marketing other insulin titration applications as well as related services, even if its products and services are in competition with the ITA Solutions.

22.4.2 Financial consideration

Verily has already paid various fixed amounts to the Company based on achievement of certain goals.

Verily also undertakes to pay the Company service fees in consideration for Company’s performance of certain support services, which are calculated according to the number of new active users of each of the ITA Solutions each quarter (*i.e.* having obtained at least one insulin dose recommendation during the two consecutive weeks following the activation by the user of an ITA Solution), the service fees varying by increments of active users, and limited to a one-time payment for each active user.

22.4.3 Intellectual property

The Company and Verily each retain their respective intellectual property rights protecting the elements created before 26 February 2016 or created separately during the term of the agreement. The intellectual property rights to jointly created elements will be jointly owned (although no joint development is contemplated by the agreement). Verily retains right in the user data and grants the Company, for the term of the agreement, a non-transferable licence to utilise user data for the purposes of supplying, improving and assessing the performance of the ITA Solutions, as well as maintaining the related regulatory approvals.

The agreement provides the option for Verily to access the source codes of the ITA Solutions if the Company discontinues its activity in relation to the ITA Solutions and has no successor to take over all of the Company’s obligations under this agreement.

22.4.4 Termination conditions

The licence and services agreement may be terminated by either party in the event of (i) a force majeure event affecting the other party for a period of more than 90 days, (ii) a material breach of the obligations of the other party, not remedied within 30 days of notification of the breach sent to that party by the first party, and (iii) suspension of payments of the other party, commencement of insolvency proceedings against it, an assignment for the benefit of creditors or the appointment of a trustee for all or a substantial portion of the assets of that other party.

Furthermore, this agreement may also be terminated at any time by Verily, subject to thirty (30) days' notice.

22.5 Non-exclusive licence and services agreement with Onduo

On 14 March 2018, the Company entered into a non-¹exclusive licence and services agreement with Onduo LLC ("Onduo"). This agreement is governed by the law of the State of Delaware (United States), and any dispute is to be referred to the competent courts of the State of Delaware.

22.5.1 [Purpose of the licensing and services agreement](#)

Under the terms of this agreement, the Company grants Onduo a non-exclusive, non-transferable, worldwide licence excluding France, with the option of granting sub-licences, (i) to incorporate the ITA 1 and/or ITA 2 solutions into the platform developed by Onduo (the "[Platform](#)"), (ii) to market and distribute ITA Solutions under the Company's brand names and/or under its own brand names, and (iii) to use the Theraxium technology platform to the extent necessary to incorporate the ITA Solutions into the Platform and to market the ITA Solutions.

The Company is responsible for (i) obtaining all necessary approvals for the manufacture, promotion, import and sale of the ITA Solutions in all countries (CE marking in the European Union and 510(k) clearance in the United States), and (ii) notification of the regulatory authorities of any safety-related event concerning the ITA Solutions.

Pursuant to this agreement, the Company undertakes to provide Onduo with corrective maintenance, hosting, server availability, backup, management, and technical support services (excluding technical support for end users).

Onduo has the option of developing, obtaining a licence for, and/or marketing other insulin titration applications as well as related services, even if its products and services are in competition with the ITA Solutions.

22.5.2 [Financial consideration](#)

During the first year of the agreement and once the ITA Solutions have been activated by a certain number of active users (i.e. having obtained a recommendation regarding the insulin dose during two consecutive weeks following the user's activation of an ITA Solution), Onduo undertakes to pay the Company a lump sum per active user of the ITA Solution, with this amount decreasing per increment of active users.

The parties undertake to negotiate in good faith in order to set the compensation, before the end of the first year, that will be owed by Onduo to the Company for each active user of the ITA Solution owed by Onduo at the end of that first year.

22.5.3 [Intellectual property](#)

The Company and Onduo each retain their respective intellectual property rights protecting the elements created before the agreement was entered into or created separately during the term of the agreement. The intellectual property rights to the items created jointly will be held in co-ownership. Onduo grants the Company, for the term of the agreement, a non-transferable licence to use the users' data for the purposes of supplying, improving, and assessing the performance of the ITA Solutions, as well as maintaining the related regulatory authorisations.

¹ Onduo is the joint venture between Sanofi and Verily.

The agreement provides the option for Onduo to access the ITA Solutions' source codes if the Company discontinues its activity in relation with the ITA Solutions and has no successor to take over all of the Company's obligations under this agreement.

22.5.4 Term

The licensing and cooperation agreement was entered into for an initial term of one year. It is automatically renewable on every anniversary date for an additional one-year term.

22.5.5 Termination conditions

The licensing and cooperation agreement may be terminated on any anniversary date by either party as long as 60 days' advance notice is given for Onduo and 120 days for the Company.

The agreement may also be terminated by either party in the event of (i) a force majeure event affecting the other party for a period of more than 90 days, (ii) a serious breach of obligations incumbent on the other party, which have not been remedied within 30 days from notice of the breach sent to that party by the first party, and (iii) suspension of payments by the other party, initiation of insolvency proceedings against it, a disposal benefiting its creditors, or appointment of a trustee to all or a substantial portion of the assets of this other party.

22.6 Bond issue agreement entered into with Kreos Capital V (UK) Ltd

On April 13, 2018, the Company entered into a dry bond issue agreement (in the form of a Venture Loan Agreement and a Bond Issue Agreement) with the English company Kreos Capital V (UK) Ltd ("Kreos"). This bond issue is divided into three tranches for an amount of €4 million (Tranche A), €1.5 million (Tranche B) and €1.5 million (Tranche C and, together, the "Kreos Bonds"). At the Company's request, all these tranches were subscribed by Kreos.

Kreos could subscribe to an additional tranche of €5 million, subject to an agreement being reached between the parties on the terms and conditions and arrangements for this additional drawdown.

Under the terms of a bond issue agreement dated the same day, the Company allocated, in consideration for the Kreos Bonds, 70,000 share warrants to Kreos Capital V (Expert Fund) L.P. (the "BSA₂₀₁₈-Kreos").

In addition, to guarantee the Kreos Bonds, the Company granted Kreos a collateral pledge on some of its assets (particularly its receivables, bank accounts, and intellectual property rights).

22.6.1 Terms of the subscribed Kreos Bonds (Tranche A)

Tranche A of the Kreos Bonds issued by the Company on 11 April 2018 has the following terms:

Nominal amount of the subscribed Kreos Bonds (Tranche A): €1

Subscription date: 11 April 2019

Amortisation: by monthly instalments starting with the 6th month after the issue of the Kreos Bonds concerned

Maturity:	36 months after the issue of the Kreos Bonds concerned
Interest rate:	11% per year as well as an end-of-loan fee of 2% to be paid on the final maturity date
Prepayment fee:	if the Kreos Bonds are voluntarily repaid before their final maturity date, the Company shall pay a fee equal to the sum of the interest that would have accrued as from the prepayment date until the final maturity date if the Kreos Bonds had not been repaid, minus (i) 10% if prepayment is made within 12 months from the settlement date, (ii) 15% if prepayment is made between the 12 th and the 24 th month from the settlement date, and (iii) 20% if prepayment is made more than 24 months after the settlement date.

Proceeds from Tranche A of the Kreos Bonds are allocated to the Group's general cash requirements.

22.6.2 Terms of the Kreos Bonds to be subscribed (Tranche B)

Tranche B of the Kreos Bonds issued by the Company on [__o__] 2019 has the following terms:

Nominal amount of Kreos Bonds to be issued (Tranche B):	€1
Subscription date:	within 12 months of 13 April 2018
Conditions precedent to the subscription:	Conversion of OC ₂₀₁₇ into capital of up to €3,550,000 and no default
Amortisation:	by monthly instalments starting with the 6 th month after the issue of the Kreos Bonds concerned
Maturity:	36 months after the issue of the Kreos Bonds concerned
Interest rate:	11% per year as well as an end-of-loan fee of 2% to be paid on the final maturity date
Prepayment fee:	if the Kreos Bonds are voluntarily repaid before their final maturity date, the Company shall pay a fee equal to the sum of the interest that would have accrued as from the prepayment date until the final maturity date if the Kreos Bonds had not been repaid, minus (i) 10% if prepayment is made within 12 months from the settlement date, (ii) 15% if prepayment is made between the 12 th and the 24 th month from the settlement date, and (iii) 20% if prepayment is made more than 24 months after the settlement date.

Proceeds from Tranche B of the Kreos Bonds were allocated to the Group's general cash requirements.

22.6.3 Terms of the Kreos Bonds to be subscribed (Tranche C)

The terms and amount of Tranche C of the Kreos Bonds issued by the Company on 11 April 2019 are identical to those of Tranche B.

22.6.4 Warrants issued for Kreos Capital V (Expert Fund) L.P.

The Company allocated 70,000 BSA_{2018-Kreos} for a total issue amount of one euro to Kreos Capital V (Expert Fund) L.P.

22.6.4.1 Terms of the shares that can be subscribed to by exercising the BSA_{2018-Kreos}

The BSA_{2018-Kreos} will confer an entitlement to subscribe for 70,000 ordinary shares of the Company with a nominal value of €0.10 at a price per share of €11.

22.6.4.2 Conditions for the exercise of BSA_{2018-Kreos}

All of the BSA_{2018-Kreos} are exercisable as of the date of the Registration Document.

The BSA_{2018-Kreos} will automatically expire on the first of the two following dates:

- 30 May 2023; and
- the date of completion of the disposal of all of the Company's shares.

22.6.4.3 Terms of the BSA_{2018-Kreos}

The BSA_{2018-Kreos} are fully transferable to any entity in the Kreos group or their affiliates.

It is specified as needed that listing of the BSA_{2018-Kreos} will not be requested.

The other terms of the BSA_{2018-Kreos} are detailed in Section 21.1.4.3 of the Registration Document.

22.6.5 Collateral granted

To guarantee repayment of the Kreos Bonds, the Company granted Kreos a collateral pledge on some of its assets:

- any Company receivable with regard to any third party resulting from the Company's usual business,
- the credit balance of all the bank accounts opened by the Company, and
- the Company's intellectual property rights (for more information on these pledged intellectual property rights, see Section 11.6 of the Registration Document).

The purpose of this collateral is to guarantee all of the Company's payment obligations for a total principal amount of €7 million (€7,000,000) which is the amount of the Kreos Bonds, as may be reflected after adding interest and any penalty interest, fees, costs, compensation, and related charges.

This collateral may be implemented by Kreos in the event of the Company's default on payment or the acceleration of the Kreos Bonds due to the occurrence of any default event as stipulated in the issue agreement and default of sums due. Implementation of any of this collateral would result in a court order, a forced sale, or, as applicable, the transfer of ownership of the pledged asset in question to Kreos.

22.6.6 [Company undertakings](#)

Under the terms of the bond issue agreement, the Company has undertaken to comply with the following obligations to Kreos:

- not to contract any financial debt other than the Kreos Bonds, subordinated bonds, or current debt for an amount greater than €100,000, financial loan and lease for current equipment of the Company, day-to-day bank facilities for an individual amount of less than €50,000, research tax credit factoring for an amount greater than €1,300,000, and subordinated credit not backed by guarantees that may be agreed with the European Investment Bank for an amount greater than €20,000,000 at any time; and,
- not to grant any new collateral or guarantee in consideration for a debt;
- not to substantially change activities;
- not to make any asset disposals other than in the normal course of business, nor any acquisitions, nor to create any joint ventures without the prior approval of Kreos;
- not to distribute dividends or fees to its shareholders;
- to comply with all of the laws and regulations applicable to it;
- not to carry out any restructuring or merger; and
- to preserve the assets required for its activity and not to enter into any transactions other than in normal business conditions.

Any non-compliance by the Company (or any of its subsidiaries) with any of these undertakings would enable Kreos to declare the acceleration of the Kreos Bonds and lead to implementation of the collateral as described in Section 22.6.4 above.

Kreos Bonds carry no obligation to comply with financial ratios.

Finally, Kreos was given the right to request that an observer be appointed to the Company's Board of Directors.

22.6.7 [Prepayment](#)

Kreos may seek the prepayment of all of the sums (principal and accrued interest) due for the Kreos Bonds in the event of:

- payment default by Kreos of any amount at its maturity;
- default on another financial debt in an amount greater than €100,000;
- violation of the Company's undertakings as listed in Section 22.6.5 above, insofar as this violation is not settled within 10 business days from the date on which Kreos notifies the Group of the violation or knowledge of the violation;
- occurrence of a change of control;
- insolvency or collective proceedings of a Group member;

- trigger of a pledge granted by a member of the Group to any other creditor, or seizure of any of its assets; or
- occurrence of any event or circumstance that results in or may result in a material adverse effect (as deemed by Kreos) on the Company's financial position or assets.

23. INFORMATION FROM THIRD PARTIES, EXPERT STATEMENTS, AND DECLARATIONS OF INTEREST

23.1 Name of experts

Non applicable.

23.2 Name of third parties

Non applicable.

24. PUBLICLY ACCESSIBLE DOCUMENTS

Copies of the Registration Document are available free of charge at the Company's head office at 58, Avenue de Wagram, 75017 Paris, France.

The Registration Document can also be viewed on the Group website (www.voluntis.com) or the AMF website (www.amf-france.org).

The Company's Articles of Association, minutes of the general meetings, and other company documents, as well as historical financial information and any assessment or statement made by an expert at the Group's request that must be made available to shareholders, pursuant to applicable law, may be consulted free of charge at the Company's head office.

As from the listing of the Company's shares for trading on the regulated Euronext market in Paris, regulated information within the meaning of the AMF's General Regulation will also be available on the Group's website (www.voluntis.com).

25. SHAREHOLDING INFORMATION

Information on the companies in which Voluntis holds a fraction of the capital likely to have a material impact on the appraisal of its asset base, financial position, or income is shown in Chapters 7 "*Organisational Chart*" and 20 "*Financial Information*" of the Registration Document.

26. CROSS-REFERENCE TABLE

CROSS-REFERENCE TABLE WITH THE ANNUAL FINANCIAL REPORT		
	Annual Financial Report	Chapter(s)/Section(s)
1	Statement of the person responsible	1.1
2	Annual company financial statements - French standards	28.1
3	Annual consolidated financial statements - IFRS	20.1
4	Management Report	See index below
5	Corporate Governance Report	See index below
7	Details of fees paid to the Statutory Auditors	2.3
8	Statutory Auditors' report on the annual financial standards in accordance with French standards and IFRS	20.2 et 28.2

CROSS-REFERENCE TABLE WITH THE MANAGEMENT REPORT		
	Management Report	Chapter(s)/Section(s)
1	Position and activity of the Company during the past year	6.1
2	Financial position: review of the financial statements and results	9.2
3	Appropriation of income and reminder of dividends paid	9.2.7
4	Non-deductible expenses	9.2.8
5	Information on payment terms of suppliers and customers	9.2.6.4
6	Progress achieved or difficulties encountered	6
7	Principal risks and uncertainties facing the Company / Use of financial instruments by the Company	4
8	Research and development activity	9.2.3.4 et 11
9	Foreseeable developments and future outlook	5.2.3
10	Significant events since the end of the financial year	5.1.5 et 2 Note 1
11	Employee shareholding	17.3
12	Significant equity investments or controlling interests in companies having their registered office in France; disposals of such equity investments	7.2
13	Activities of subsidiaries and controlled companies	7.2
14	Information on the shareholder structure and treasury shares – Share buyback programme	21.1.3
15	Changes to the shareholder structure during the year	21.1.7
16	Change in share price – Risk of changes in share price	21.1.7.3
17	Summary report on trading by officers and the persons referred to in Article L. 621-18-2 of the French Financial and Monetary Code in the shares of the Company during the past year.	15.5

CROSS-REFERENCE TABLE WITH THE MANAGEMENT REPORT		
	Management Report	Chapter(s)/Section(s)
19	Allocation of free shares and stock options	21.1.4
20	Table of results for the last five years	9.2.9
21	Internal control and risk management procedures set up by the Company	16.5

CROSS-REFERENCE TABLE WITH CORPORATE GOVERNANCE REPORT		
	Corporate Governance Report	Chapter(s)/Section(s)
1	Composition of the Board of Directors	14.1.2
2	Balanced representation of women and men on the Board of Directors	16.3.1
3	Executive management procedures	16.1
4	Review of members' independence and potential conflicts of interest	14.2 et 16.3.1
5	Tasks of the Board of Directors	16.3
6	Conditions for the preparation and organisation of the tasks of the Board of Directors	16.3
7	Agreements concluded between an officer or a significant shareholder of the Company and a subsidiary	16.2 et 19.2
8	Compensation paid to corporate officers	15.1
9	Principles and criteria for determining, distributing and assigning the fixed, variable and exceptional components composing the total compensation and benefits of any kind attributable to the Chairman of the Board of Directors, Chief Executive Officer and Deputy Chief Executive Officers	15.4
10	Specific arrangements for the participation of shareholders in the Company's General Meeting	21.2.5
11	Items likely to have an impact in the event of a public offering	18.8
12	Summary table of the status of currently valid delegations of authority and powers granted by the General Meeting of shareholders to the Board of Directors with respect to capital increases and the use made of these delegations in the past year	21.1.5

27. GLOSSARY

A1c (or HbA1c)

Glycated haemoglobin. Glycated haemoglobin is measured for the long-term monitoring of diabetes mellitus, a chronic condition involving the insufficient production of insulin by the pancreas or the ineffective use of the insulin produced in the body. People with poorly controlled diabetes have a high level of glycated haemoglobin in their red blood cells. This level is expressed as a percentage or in millimoles per litre (mmol/mol). The percentage of HbA1C therefore represents the way to monitor glycemic control during the past three months and is used by doctors as a marker of a patient's glycemic balance and in clinical studies to measure the significance of the effect of a treatment on glycemic control. The glycemic level recommended by medical authorities is a HbA1c level of less than 6.5% in Europe and less than or equal to 7% in the United States.

Chemotherapy

Treatment of cancer by chemical substances which kill or weaken cancerous cells. Chemotherapy is a general treatment which seeks to destroy cancerous cells or prevent them from multiplying throughout the body. There are many chemotherapy medications and these are often used together in order to increase the effectiveness of the treatment. They can be administered by perfusion, injection or in the form of tablets. Chemotherapy medications affect both cancer cells and healthy cells that divide rapidly, which can cause secondary effects: nausea, vomiting, loss of hair, fatigue, etc.

Complications of diabetes

Complications of diabetes are chronic and acute diseases due to the absence or ineffectiveness of the hormone insulin. These chronic complications include retinopathy (a disease of the eyes), nephropathy (kidney disease), neuropathy (nerve damage), cardiovascular disease (diseases of the circulatory system) ulceration of the foot and amputation.

Diabetes

Diabetes occurs when the body is not able to produce enough of the hormone insulin or cannot use it effectively.

Type 1 diabetes

Type 1 diabetes is found most frequently in children and adolescents. Around 10% of diabetics have Type 1 diabetes. Insulin is the lifetime treatment for patients with Type 1 diabetes.

Type 2 diabetes

Type 2 diabetes is more widespread than Type 1 and mainly affects adults. Type 1 symptoms can also affect people affected by Type 2 diabetes, albeit in a less pronounced way. However, some patients suffering from Type 2 diabetes do not have early symptoms and are only diagnosed several years after the disease presents itself, although the various complications are already present. Type 2 diabetics may need to be treated with hypoglycaemic medications and may also go on to need insulin injections.

FDA

The Food and Drug Administration (FDA or US FDA) is a federal agency of the United States Department of Health and Human Services. It is one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of several medical areas and applications that come under its jurisdiction.

Glucose

Sugar produced within the body from proteins, fats and carbohydrates. Glucose is the main energy source for living cells and it supplies them by means of the bloodstream. The cells cannot, however, use the glucose without the help of insulin.

Glycated haemoglobin (HbA1c)

See A1c

HFE

See usability

HIPAA

English acronym of Health Insurance Portability and Accountability Act, is a law on health and health insurance passed by the United States Congress in 1996. In particular, this law governs the use of health data.

Hyperglycemia

Hyperglycemia is the term describing an abnormally high level of glucose (sugar in the bloodstream). This high amount of glucose occurs when the body does not make enough insulin or does not manage to use it correctly

Hypoglycemia

Hypoglycemia is the term describing an abnormally low level of glucose (sugar in the bloodstream).

Immunotherapy

Treatment seeking to stimulate the body's defences, particularly against cancerous cells when it is used as an anti-cancer treatment.

Insulin

Hormone whose principal action allows the cells in the body to absorb the glucose in blood and transform it into a source of energy. Insulin is produced by the pancreas.

Insulin – animal, human and analogue

Insulin replacement therapies have used insulin production since 1925. Initially, it was extracted from bovine and porcine pancreases. Technologies that were developed at the beginning of the 1980s enabled biosynthetic human insulin to be produced, replacing animal insulin. Insulin analogues were developed to overcome the limits of subcutaneously injected human insulin. They have now replaced human insulin.

The different types of insulin are also classified according to their action within the body and, more specifically, according to the speed with which they begin to act, their maximum effect and their duration of action. Rapid-acting insulin analogues have an accelerated effect while slow insulin analogues last longer with a more continuous effect and no peak effect.

Therapeutic software

Therapeutic software refers to mobile and web applications that deliver recommendations to both patients and healthcare professionals to optimise treatment efficacy.

Symptom

Abnormal indication caused by an illness (discomfort, pain, burning, choking sensation, fatigue, nausea, etc.). A symptom may be experienced differently by different patients.

Telemedicine or Telemedicine Service

Telemedicine is a form of remote medical practice using information and communication technologies. It connects one or more healthcare professionals or healthcare professionals with a patient, which must include a medical professional (doctor, midwife, dental surgeon) and, where relevant, other professionals providing care to the patient.

Basal treatment

Insulin therapy that allows the sugar concentration in the bloodstream to be controlled between meals and during sleep is called long-acting insulin or basal insulin.

Basal-bolus treatment

A bolus consists of a subcutaneous injection of rapid-acting insulin in order to cover intakes from meals or snacks. MDI treatment Multiple dose injection (MDI) treatment, which involves at least three daily injections, remains the most common method for intensive insulin treatment. Daily multiple injections involve both injecting long-acting insulin once or twice a day in order to carry a basal dose and other rapid-acting insulin injections at each meal time.

Usability

Usability may be defined as the fitness of an object or service to be used easily by an individual in accordance with its intended purpose and effectively, efficiently and satisfactorily. Usability is an English term.

28. APPENDIX

28.1 Company financial statements prepared in accordance with French standards for the financial year ended 31 December 2018

Assets

(in €)	Gross	Deprec. and amort.	Net 31/12/2018	Net 31/12/2017
Uncalled share capital				
FIXED ASSETS				
Intangible assets				
Start-up costs	222,466	222,466		
Research and development costs				
Patents, licences, software, rights & similar securities	7,099,682	4,223,730	2,875,952	2,749,268
Commercial funds (1)				
Other intangible assets	791,217		791,217	992,251
Advances and prepayments on intangible assets				
Tangible assets				
Land				
Buildings				
Technical facilities, equipment and industrial machinery				
Property, plant and equipment	1,206,715	672,901	533,814	736,263
Other tangible assets				
Advances and prepayments				
Financial assets (2)				
Investments (equity method)				
Other investments	873	834	40	
Receivables from equity interests	1,892,805	0	1,892,805	1,301,717
Other capitalised securities				
Loans				
Other financial assets	496,028	79,668	416,360	209,195
TOTAL FIXED ASSETS	11,709,787	5,199,599	6,510,188	5,988,694
CURRENT ASSETS				
Inventory and work in progress				
Raw materials and other supplies				
Work in progress (goods and services)				
Intermediate and finished goods				
Commodities				
Advances and prepayments paid on orders				
Receivables (3)				
Trade and other receivables	1,443,989	19,680	1,424,309	321,489
Other receivables	4,111,088		4,111,088	2,177,571
Uncalled, unpaid share capital				
Sundry				
Investment securities				
Liquid assets	19,570,951		19,570,951	1,695,026
Prepaid expenses	279,544		279,544	99,781
TOTAL CURRENT ASSETS	25,405,572	19,680	25,385,892	4,293,867
Loan issue costs to be amortised				
Bond repayment premiums				
Foreign exchange differences - assets	1,365		1,365	2,115
GRAND TOTAL	37,116,724	5,219,279	31,897,446	10,284,677
(1) Including right to lease				

(2) Of which less than one year (gross)				
(3) Of which more than one year (gross)				

Liabilities

(in €)	31/12/2018	31/12/2017
Shareholders' equity		
Capital	757,566	480,208
Issue, merger, contribution premiums, etc.	70,354,464	35,752,109
Revaluation difference		
Legal reserves		
Statutory or contractual reserves		
Regulated reserves		
Other reserves		
Retained earnings	-34,694,182	-25,235,926
Profit (loss) for the year	-13,899,076	-9,458,256
Investment subsidies		
Regulated provisions		
TOTAL SHAREHOLDERS' EQUITY	22,518,773	1,538,136
OTHER EQUITY		
Proceeds from the issue of equity securities		
Conditional advances	297,500	510,000
TOTAL OTHER EQUITY	297,500	510,000
Provisions		
Provisions for liabilities	78,209	78,959
Provisions for expenses		
TOTAL PROVISIONS FOR LIABILITIES AND EXPENSES	78,209	78,959
DEBT		
Convertible bond loans	3,580,111	3,653,907
Other loans		
Loans and borrowings from credit institutions (2)		1,240
Miscellaneous interest bearing loans and borrowings (3)		169,984
Advances and prepayments received on orders		
Accounts payable and related accounts	2,963,048	1,884,159
Tax and social security debts	2,015,240	1,925,556
Debts on fixed assets and related accounts		
Other debts	17,949	
Deferred income (1)	368,815	522,633
TOTAL DEBT	8,945,164	8,157,479
Foreign exchange differences - liabilities	57,799	103
GRAND TOTAL	31,897,446	10,284,677
(1) Of which more than one year (a)		
(1) Of which less than one year (a)	8,945,164	8,157,479
(2) Of which bank borrowings and bank credit balances		1,240
(3) Of which participation loans		
(a) Excluding advances and prepayments received on orders		

Statement of profit or loss (1st part)

	France	Exports	31/12/2018	31/12/2017
(in €)				
Operating income (1)				
Sales of goods				
Sold production (goods)				
Sold production (services)	1,936,049	2,550,810	4,486,859	7257584
Net revenue	1,936,049	2,550,810	4,486,859	7,257,584
Stocked production				
Capitalised development costs			2,140,967	1,602,110
Operating subsidies			1,000	9,837
Reversals of provisions (and depreciation), transfers of charges			2,964,367	62,869
Other income			952	11,525
Total operating income (1)			9,594,144	8,943,926
Operating expenses (2)				
Purchases of goods				
Inventory variations				
Purchases of raw materials and other supplies				
Inventory variations				
Other purchases and external expenses (a)			12,832,208	8,457,988
Taxes, duties and other levies			305,342	289,613
Salaries and wages			6,081,400	6,115,837
Payroll expenses			2,990,010	2,855,038
Depreciation, amortisation				
- On fixed assets: amortisation allowances			2,453,527	1,934,575
- On fixed assets: depreciation allowances				
- On current assets: depreciation allowances				
- For risks and expenses: provisions			0	76,844
Other expenses			377,889	165,138
Total operating expenses (II)			25,040,376	19,895,033
			-	-
OPERATING PROFIT (I-II)			15,446,232	10,951,108
Share of profit on operations made jointly				
Profit allocated or loss transferred (III)				
Loss sustained or profit transferred (IV)				
Financial income				
From investment (3)				
From other securities and receivables from fixed assets (3)				
Other interest and similar income (3)			33,571	27,713
Reversals of provisions (and depreciation), transfers of charges			148,113	1,619
Positive currency differences			31,314	4,274
Net proceeds on disposal of securities			745	0
Total financial proceeds (V)			213,742	33,606
Financial expenses				
Depreciation, amortisation and provisions			250,364	2,126
Interest and similar expenses (4)			447,229	192,674
Negative currency differences			40,587	60,722
Net expenses on disposal of securities			15,521	0
Total financial expenses (VI)			753,701	255,521
FINANCIAL INCOME (V-VI)			-539,958	-221,915

CURRENT INCOME before taxes (I-II+III-IV+V-VI)	15,986,190	11,173,023
---	-------------------	-------------------

Statement of profit or loss (2nd part)

(in €)	31/12/2018	31/12/2017
Exceptional income		
On management operations	300,300	0
On capital transactions		
Reversals of provisions and depreciation and transfers of charges		
Total exceptional income (VII)	300,300	0
Extraordinary expenses		
On management operations	3,640	60
On capital transactions		
Depreciation, amortisation and provisions		
Total financial expenses (VIII)	3,640	60
EXCEPTIONAL INCOME (VII-VIII)	296,660	-60
Employee profit sharing (IX)		
Taxes on profits (X)	-1,790,454	-1,714,827
Total operating income (I+III+V+VII)	10,108,186	8,977,532
Total expenses (II+IV+VI+VII+IX+X)	24,007,262	18,435,787
PROFIT OR LOSS	-13,899,076	-9,458,256
(a) Including:		
- Moveable property leasing fee		
- Real estate leasing fee		
(1) Of which profits relating to prior financial years		
(2) Of which expenses relating to prior financial years		
(3) Of which profits relating to related entities	33,571	
(4) Of which interests relating to related entities	161,762	

NOTES TO THE ANNUAL FINANCIAL STATEMENTS

AT 31 DECEMBER 2018

The financial year ended 31 December 2018 had a duration of 12 months.
Unless otherwise indicated, the figures shown are in thousands of euros.

The financial statements were approved by the Company's Board of Directors on 19 March 2019.

The pre-allocation balance sheet for the year ended **31/12/2018**, whose total was **€31,897,446**, generated a loss of **€13,899,076**.

The notes and tables below form an integral part of the Company accounts.

1. BUSINESS OVERVIEW AND SIGNIFICANT EVENTS IN THE FINANCIAL YEAR

1.1 Nature of the Company's business and its history

Voluntis develops and markets therapeutic software to help patients with chronic conditions and improve treatment outcomes.

Our mobile app and web-based digital solutions deliver personalised recommendations directly to patients and their care teams. Uses include dose adjustment, managing side effects, monitoring symptoms and automatic remote analysis of patient results. The recommendations are generated immediately by digitised medical algorithms built on sound scientific intelligence and reinforced by multiple security regulations. While our digital therapeutics are new-generation health solutions, they are classified as healthcare products, which must be approved in clinical trials and submitted for regulatory approval (EC marking in France, FDA approval in the United States). They are available on medical prescription and may be eligible for reimbursement by payers.

Voluntis has two therapeutic solutions for diabetes, Insulia® and Diabeo®, both of which are in the marketing phase, following an extensive clinical trial programme conducted in partnership with Sanofi and the French centre for diabetes research and treatment, CERITD. Insulia® is now in the process of being launched through two complementary channels: direct sales, by approaching payer organisations, and indirect sales through non-exclusive distribution partners. Diabeo® is intended for type 1 and type 2 diabetes (T1D and T2D) patients treated on a multi-injection or insulin pump regimen. It has regulatory approval in Europe and is being marketed by Sanofi.

Our oncology offer is under development. The aim of the solutions is to improve patient adherence to their treatment regime. Voluntis is developing a therapeutic solution targeting a range of different cancers, as well as specific solutions under partnership agreements with the pharmaceutical industry.

1.2 2018 key events

Commercial and business development

Voluntis began the commercial launch in France and North America of its Diabeo® and Insulia® solutions in January 2018, together with its partners.

In the United States, the Group is pursuing the creation of its direct sales team with paying bodies, which is reflected in hiring in the sales, marketing, and medical fields.

At the same time, the Group has extended its marketing partnerships in the United States. As such, on 9 January 2018 a new partnership was announced with Welldoc.

In Oncology, the Group met the Food & Drug Administration (the "FDA") in January 2018 at a pre-submission meeting, to lay out the regulatory approval process for its multi-cancer monitoring platform.

Moreover, also in oncology, in March 2018 the Group announced that it was extending its partnership with Roche, with a view to developing and marketing a multi-indication solution in France.

The Group actively participates in the sectoral work of the Digital Therapeutics Alliance.

Finally, on 3 May 2018, the Company entered into an agreement with a US payer, WellDyneRx (Pharmacy Benefit Manager managing approximately 850,000 insured persons in the targeted commercial segment). This agreement covers the promotion, price and reimbursement conditions of its Insulia solution by WellDyneRx in the United States of America. Insulia's terms and conditions of coverage set out in this agreement are in line with standard terms and conditions applied to direct marketing to US payers.

Financing

On 29 May 2018, the Company announced that it had successfully completed an IPO on the Euronext Paris regulated market and raised €30.1 million (gross, excluding related costs).

The convertible bonds subscribed in July 2017 and January 2018 and the corresponding accrued interest were converted into share capital at the time of the Company's IPO.

In addition, under a Venture Loan Agreement and a Bond Issue Agreement entered into by the Company and Kreos Capital V (UK) Ltd. on 1 May 2018, the latter paid the nominal amount of €4 million of the bonds issued by the Company. Similarly, Kreos Capital V (Expert Fund) L.P. subscribed 70,000 warrants (the BSA_{2018-Kreos}), allocated by the Company in consideration for these bonds.

At end December 2018, the Company had €19.6 million in available cash.

Product developments and Research & Development

The Group continued investing in its two main therapeutic focuses by:

- enhancing the functionalities and coverage of its diabetes products to hold on to its leadership position and open new geographic and demographic market segments through the inclusion of a new language; and
- developing its cancer treatment platform, Theraxium Oncology.

Governance

By means of a resolution of the Extraordinary General Meeting of 11 April 2018, shareholders approved the change in the Company's method of administration and management and agreed to move from being a French société anonyme (limited liability company) with supervisory and management boards to being a French société anonyme with a board of directors.

This change was accompanied by the reappointment of some officers and by the arrival of three new independent directors so that the composition of the governance bodies complies with the regulations and requirements of the Middlednext Code, as chosen by the Company.

1.3 Change of method

No change of method took place during the financial year.

1.4 Post-closing events

On 12 March 2019, the Company notified Kreos of its wish to exercise the option to drawdown the additional tranches provided for in the Venture Loan Agreement entered into with Kreos, which was signed on 13 April 2018, for a total of €3 million. The payment of this amount will entitle Kreos to exercise 30,000 additional warrants (BSAs).

In addition, on 28 February 2019, the Company received the amount of €1,684,903 corresponding to the repayment of the 2017 research tax credit (RTC). The tax authority applied interest on overdue payments at a rate of 2.4% (from May 2018 to February 2019) to the repaid RTC as the repayment was late.

1.5 Going concern

The going concern assumption was retained by the Group's Management based on the following items:

Management has forecast the future cash flows required to market its products. These forecasts show that the Company currently has the necessary financing for its development during the 12 months following the closing date of these financial statements.

In particular, management has taken account of the following probable sources of financing in 2019:

- the drawdown of additional tranches provided for in the agreement signed with Kreos for an amount which may be up to €3 million;
- the ability to use the 2018 RTC when it becomes due.

In the longer term, according to its sales growth, the Group will look to obtain future funding in addition to new revenue from commercial agreements, particularly by putting in place new lines of borrowing, but also through recourse to the market involving current shareholders and new investors.

Thus, the Company believes that it has sufficient resources to pursue its activities for the foreseeable future. For this reason, it has prepared its financial statements according to the going concern principle.

2. ACCOUNTING PRINCIPLES AND METHODS

The financial statements have been prepared in accordance with the regulations of the Autorité des Normes Comptables (French national accounting standards body) No. 2018-01 of 5 June 2018, relating to the General Accounting Plan.

General accounting conventions have been applied in accordance with the General Accounting Plan, in line with the principle of prudence, and according to the following basic assumptions:

- ongoing concern;
- independence of financial years;
- consistent accounting principles from one financial year to the next;

and in accordance with the general rules for preparing and presenting annual financial statements.

Only significant information is stated. Except where otherwise mentioned, the amounts are stated in thousands of euros.

The basic method used when stating the value of items in the financial statements is the historical cost method.

The principal methods used are described below.

3. ASSESSMENT METHODS

3.1 Research and development costs

Research costs are expensed as incurred.

Software development expenditure is recognised as an intangible asset when the following criteria are met:

- a specific individual project has a serious chance of being successful in technical terms and commercially profitable;
- the Company intends to complete, market and support the software in question on a long-term basis;
- the Company is able to evaluate reliably the expenses attributable to intangible assets during its development.

The part recognised as intangible asset is related to the costs allocated to detailed specification activities, programming, testing and software documentation during active marketing that are likely to generate revenue for Voluntis.

The software created is amortised over the useful life of the asset, taking into account the estimated rate of obsolescence and renewal of the functions developed in one year.

At 31 December 2018, all software amortised was subject to amortisation over three years. This period is calculated individually for each software programme. Capitalised developments costs are amortised when one of the following occurs:

- Signature by D.O. (Design Output) for products already marketed and covered by regulatory approvals for the version in question;
- when the first regulatory approval is obtained;
- recognition of the first euro in revenue.

3.2 Other intangible assets

Non-amortisable intangible assets correspond to business goodwill, which is not amortised; it is subject to a regular assessment on the occurrence of events likely to call into question its value. Where its present value, based on the criteria that prevailed at the time of its acquisition, proves to be lower than its net book value, an impairment is recognised.

Other intangible assets correspond essentially to the software acquired and amortised over periods between 1 and 3 years depending on the expected useful life time.

Any transfer duties, fees, commissions or transaction costs on intangible assets are recognised in expenses.

Any borrowing costs related to the acquisition of assets are also recognised as expenses.

3.3 Tangible assets

These are expenses that meet the following criteria:

- the asset is held by the entity either for use in the production or supply of goods and services, or for leasing to third parties or for administrative purposes.
- the estimated useful life exceeds one financial year.
- the expense incurred will generate future economic benefits.
-

Tangible assets are recorded in the balance sheet at their acquisition or production cost.

The straight-line method of depreciation is used for economic depreciation. The tax possibilities of additional depreciation are recorded as exceptional depreciation.

Depreciation is calculated based on the following useful life of the asset:

	Term	Method
Fixtures and technical installations	5 years	Linear
Computer equipment	3 years	Linear
Office equipment and furniture	5 years	Linear

At each year-end, if there is any indication that an asset has lost significant value, a depreciation test is performed. The recognition of a depreciation will change the depreciable base of the asset concerned.

The linear depreciation method for computer equipment has been applied since 1 January 2018. It was preferred to the declining method, because the calculation of the depreciation of the equipment corresponds better to its use and thus to the economic reality.

3.4 Holdings and other equity securities

Fixed assets are valued at their acquisition cost.

At the end of each financial year, the value in use of the holding is examined. Where this value is lower than the book value, a provision is made for the amount of the difference.

3.5 Receivables

Receivables are valued at their nominal value. A depreciation is applied when the inventory value is lower than the book value.

3.6 Operating receivables

Receivables are valued at their nominal value. A depreciation is recognised in the event of litigation or uncertainty as to the timing of their recovery.

3.7 Investment securities

Investment securities are stated at their acquisition value and are accounted for using the FIFO method.

Where the inventory value, corresponding to their market value, is lower than their acquisition cost, a depreciation of these securities is made up in the amount of the difference.

3.8 Shareholders' equity

Share capital (see Note 8)

Shares and other subscribed instruments are classified in shareholders' equity.

The costs of capital operations (capital increase, merger, spin-off, etc.) directly attributable to the issue of shares or new options are recognised in shareholders' equity less the proceeds from the issue, and then in expenses if the premiums are insufficient.

3.9 Conditional subsidies and advances

Subsidies and grants that the Company may receive are recognised where there is reasonable assurance that the Company will comply with the conditions attached to the subsidies or grants and that they will be received.

The part of the public subsidy or grant to be received either as compensation for expenses already incurred or as direct financial support to the Company without future costs is recognised as income in the year in which the subsidy or grant is acquired.

Innovation or investment grants received in the form of conditional advances, which are repayable in whole or in part according to the technical success of a programme, are recognised in other equity.

3.10 Provisions

In accordance with CRC Regulation No. 2000-06 on assets, any obligation of our Company towards a third-party, which can be estimated with sufficient reliability and giving rise to a probable outflow of resources without compensation, is recognised as a provision. The amount recognised is the best estimate of the expenditure needed to settle the obligation.

The other provisions made are intended to cover the risks and expenses clearly specified in terms of their purpose and amount, which events occurring or in progress make probable.

Loss making contracts give rise, if necessary, to a provision for loss on completion. As at 31 December 2018, no provisions for risks and expenses on commercial contracts were recognised.

3.11 End-of-career benefits

Retirement commitments:

The plan is a fixed contribution plan in France and is not subject to a provision in the annual financial statements. When employees retire, they receive end-of-career benefits according to the rules set out in the collective agreements.

These commitments were calculated at the end of the financial year on the basis of the following assumptions:

Retirement age	67 years
Estimated inflation rate	1%
Rate of salary increase	2%
Employer's contribution rates	50%
Discount rate	1.8%
Degressive employee rotation by age (weighted average)	20%

The estimated amount of non-recognised chargeable IFCs amounts to €207 k as of 31 December 2018.

3.12 Long-service awards

No provision has been recognised due to the insignificant nature of this item.

3.13 Transactions in foreign currencies

Transactions in foreign currencies are converted on the day of the transaction date. Balances of assets and liabilities denominated in foreign currencies are translated at the closing exchange rate, and unrealised foreign exchange gains and losses resulting from these conversions are recorded in the statement of profit or loss.

The difference resulting from the discounting of debts and receivables in foreign currencies at the latter price is recorded in the balance sheet as "Foreign exchange differences".

Unrealised foreign exchange losses are subject to a provision for risks, in full.

3.14 Revenue recognition

Revenue includes user licensing fees, set-up services, subscriptions, support and maintenance services, as well as amounts linked to contractual milestones.

Revenue from the sale of products and services is generally recognised when the risks and rewards of ownership have passed to the buyer. The rule applied by income category is detailed below:

General cases

Licensing revenue

Licensing revenue is recognised to the extent the following conditions have been fulfilled: there is proof of a formalised agreement through a contract or a signed order, the delivery of the product was accompanied by a delivery note or a signed record of receipt for the installation, the price is determined or determinable, the recovery of the liability is probable.

Licences invoiced in instalments, which have been delivered over the period, may lead the Company to recognise the invoices to be issued for the outstanding amount on the closing date.

If the provision of services involves a substantial modification to the licensed software or has a degree of complexity that is greater than the projects usually performed and likely to involve specific risks linked to their completion, the revenue generated from the licence is recognised according to the stage of completion.

Revenue from licences granted for a given period is recognised taking into account the proportion of this period over the reporting period.

Services revenue (Specific Developments, Integration, Support)

Revenue from set up services is recognised by reference to the stage of completion. As a result, the Group recognises deferred income for the services invoiced but not rendered on the reporting period. Likewise, unbilled revenue is recognised for the share of services rendered but not invoiced, considering the stage of completion.

Subscription and Maintenance revenue

Subscription (licensing in Software as a Service or SaaS and hosting) and maintenance revenue is spread over the contract period.

As a result, the Group recognises deferred income for the services invoiced but not rendered on the reporting period.

Royalty revenue

Revenue is recognised depending on the terms of the agreement applicable for the period, where the base for determining royalties is reliably known and there is reasonable reassurance that the related receivables will be settled.

Collaboration and distribution agreements

The Group concludes collaboration agreements for development and marketing which include several combined obligations (such as a licence, service provisions, hosting and support), which may be the object of a single contract or different contracts, but which in substance constitute the same contract.

These agreements may consist of a non-repayable upfront payment, technology licensing revenue, milestone or stepped payments (regulatory, clinical, linked to marketing, performance, etc.) and user licencing fees.

Upfront payments will be accrued and carried over into revenue when the collaboration agreement is signed, or deferred or spread out based on the nature of the underlying items.

Milestone payments represent the amounts, received from the co-contractor, the payment of which depends on the completion or success of certain technical, clinical, regulatory or commercial milestones.

These milestone payments are recognised when the trigger event is confirmed, when there is no residual risk regarding the milestone and when the Company has no more services to provide with regards to this event or obligation to the co-contractor, including the obligation of subsequent repayment. The trigger events may be commercial or clinical performances obtained by the Company or the other party to the agreement, regulatory authorisation or the marketing of the products developed under the agreement.

Licensing and subscription revenue from the agreements is recognised according to the general case presented above.

Revenue from set-up, assistance or advisory services rendered under the contract is recorded according to the general case presented above.

3.15 Other income

Subsidies

Due to its innovative activities, the Group receives subsidies or government grants. These subsidies and grants are recognised as "Other operating income" in the financial year that recorded the corresponding charges, where the payment of the subsidy or grant is reasonably assured.

Research tax credit

The research tax credit (CIR) is granted to companies by the tax authorities to promote technical and scientific research. The expenses incurred by the Company which fulfil the required criteria are declared by it. The Company benefits from a tax credit that can be offset against income tax returns. Under specific conditions, the unused portion of the CIR (or RTC) can be refunded. The income from the RTC is recorded in the "Income tax" line of the profit and loss statement in the year to which the eligible expenses relate.

3.16 Evaluation criteria used for the identification of exceptional operations

Items not related to the Company's ordinary activities are recognised in extraordinary income. Items of ordinary activities that are exceptional in terms of frequency or amount are included in current operating income.

3.17 Statutory Auditors' fees

Summary of the fees of the Statutory Auditors and members of their networks accounted for by financial year:

Amount (euros excl. VAT)	EY/RBB	
	2018	2017
Audit		
Statutory audit, certification, examination of individual and consolidated financial statements	144,985	80,000
Other due diligence and services directly related to the Statutory Auditors' mission	30,015	9,794
TOTAL	175,000	89,794

4. START-UP COSTS

The start-up costs recognised at year-end correspond to the fees and expenses related to the capital increases recorded up to the end of 2011. They are fully amortised at 31/12/2018.

5. FIXED ASSETS (gross amount)

Fixed assets break down as follows:

	Gross values start of year	Increase by acquisitions	Disposal by Scrapping or sale	Gross value end of the year
Intangible assets				
Start-up costs	222			222
Capitalised development costs	6,160	2,342	1,675	6,826
Developments in progress to be capitalised	992	2,141	2,342	791
Other intangible assets	273			273
Total intangible assets	7,648	4,483	4,017	8,113
Tangible assets				
General installations, fixtures and fittings	607			607
Transportation equipment				
Office and computer equipment, furniture	775	49	224	600
Advances and prepayments				
Total tangible assets	1,382	49	224	1,207
Financial assets				
Other investments	1			1
Receivables from equity interests	1,302	4,299	3,708	1,893
Loans and other financial assets	209	732	445	496
Total financial assets	1,512	5,031	4,153	2,390
GRAND TOTAL	10,541	9,563	8,395	11,710

Of the total research and development costs for the period, software development costs were recorded at €4,483 k, of which €2,342 k were amortised over a period of three years from their capitalisation and €2,141 k in assets under construction for the versions pending marketing approval.

Some capitalised developments, fully amortised and replaced in the solutions by another version, were released from intangible assets for an amount of €1,675 k.

The capitalised amount is included in other operating income in the statement of profit or loss and its breakdown by therapeutic area is as follows:

Therapeutic area	Amount capitalised in 2018	Cumulative gross value
Diabetes	3,764	6,046
Oncology	719	719
Platform	0	852
Total	4,483	7,617

Development costs that do not meet all the criteria for activation have been recognised as expenses.

6. DEPRECIATION

DEPRECIABLE ASSETS	Value at the beginning of the year	Increase by provisions	Disposal by sales	Value at the end of the year
Intangible assets				
Set-up and development costs	222			222
Capitalised development costs	3,415	2,213	1,673	3,955
Other intangible assets	268	0	0	268
Total intangible assets	3,906	2,213	1,673	4,446
Tangible assets				
General installations, fixtures and fittings	78	121	0	199
Transportation equipment				
Office and computer equipment, furniture	568	120	214	474
Advances and prepayments				
Total tangible assets	646	241	214	673
GRAND TOTAL	4,552	2,454	1,887	5,119

Depreciation of intangible assets

On the basis of the estimated obsolescence of the developments and technological renewal, the Company has opted for a depreciation period of three years. Regularly, and at least once a year, current and past development programmes that have been capitalised are reviewed to ensure they still meet the conditions to be assigned or maintained as assets.

Capitalised development costs were amortised in the amount of €2,213 k over the period.

7. DEPRECIATION OF FINANCIAL ASSETS

DEPRECIATION OF FINANCIAL ASSETS	Value at the beginning of the year	Increase by provisions	Disposal by sales	Value at the end of the year
Investments accounted for by the equity method				
Other investments	1	0	0	1
Receivables from equity interests	0			0
Loans and other financial assets			80	80
Total depreciation of financial fixed assets	1	80	0	81

8. COMPOSITION OF THE SHARE CAPITAL

The Company was listed on the Euronext regulated market in Paris on 29 May 2018, as part of a global offering to raise a gross amount of €30.1 million by means of a capital increase.

A total of 2,150,000 shares were created, with a nominal value of €0.10 per share combined with a share premium of €13.90. The convertible bonds 2017 were converted into 615,577 shares with a nominal value of €0.10 combined with a share premium of €13.90.

At 29 May 2018, the total number of shares was 7,575,661 fully subscribed and paid up shares with a nominal amount of €0.10.

At 31 December 2018, share capital therefore amounted to €757,566.10. This number excludes share subscription warrants (BSAs), founders' stock options (BSPCEs), stock options (OSAs) and allocations of free shares (AGAs). Share capital solely comprises ordinary shares.

2018 Financial year	Shares
Existing shares at the beginning of the financial year	4,802,084
Proceeds from capital increase during the IPO	2,150,000
Proceeds from capital increase through conversion of OCs ₍₂₀₁₇₎	615,577
Exercise of subscription warrants	8,000
Total shares at year-end	7,575,661

9. CHANGE IN SHAREHOLDERS' EQUITY

In € thousands	2018 Financial year
Opening shareholders' equity	1,538
Proceeds from capital increase (nominal and premium)	34,706
Subscription warrants (BSAs)	174
2018 profit/(loss)	-13,899
Closing shareholders' equity	22,519

10. INSTRUMENTS GIVING ACCESS TO CAPITAL

The Company has issued subscription warrants (BSAs), founders' stock options (BSPCEs) and allocations of free shares whose valid part at 31 December 2018 is broken down as follows:

• Founders' stock options valid at 31 December 2018

General Meeting	04/04/2014			30/06/2017	11/04/2018
	Founders' stock options/Subscription warrants	Founders' stock options/Subscription warrants	Founders' stock options/Subscription warrants	Stock options/Subscription warrants	Subscription warrants
Type of authorised instruments					
Total authorised quantity	177,955	367,460	367,460	100,000	367,460
Term of the authorisation	18 months	18 months	18 months	38 months	18 months

Management Board or General Meeting grant date	02/07/2015	30/07/2015	30/07/2015	17/07/2017	25/10/2018
Number of options allocated	28,284	20,483	12,200	22,500	
Type of Instrument	Subscription warrants	Subscription warrants	Subscription warrants	Subscription warrants	Subscription warrants
Financial year starting points	02/07/2015	30/07/2015	30/07/2015	17/07/2017	25/10/2018
Term of validity	10 years	10 years	10 years	10 years	10 years
Exercise price	€8.07	€11.00	€11.00	€11.00	
Exercised at	0	0	0	0	
Expired	0	0	0	0	
Valid at	28,284	20,483	12,200	22,500	

Number of potential shares	28,284	20,483	12,200	22,500
-----------------------------------	---------------	---------------	---------------	---------------

- **Founders' stock options valid at 31 December 2018**

General Meeting	04/04/2014			04/04/2014		13/06/2016		Total
	Founders' stock options/Subscription warrants			Founders' stock options/Subscription warrants		Founders' stock options		
Type of authorised instruments								
Total authorised quantity	177,955			367,460		75,000		748,915
Term of the authorisation	18 months			18 months		responsibilities		

Management Board or General Meeting grant date	05/06/2014	01/06/2015	01/06/2015	30/07/2015	30/09/2015	13/06/2016	22/06/2016	
Number of options allocated	132,671	5,000	10,000	206,000	38,000	75,000	128,500	595,171
Type of Instrument	Founders' stock options	Founders' stock options	Founders' stock options	Founders' stock options	Founders' stock options	Founders' stock options	Founders' stock options	
Financial year starting points	05/06/2014	01/06/2015	01/06/2015	30/07/2015	30/09/2015	13/06/2016	22/06/2016	
Term of validity	10 years	10 years	10 years	10 years	10 years	10 years	10 years	
Exercise price	€8.07	€8.07	€8.07	€11.00	€11.00	€11.00	€11.00	
Exercised at	0	0	0	0	0	0	0	
Expired	-8,898	0	0	-16,000	-10,000	0	-18,000	-52,898
Valid at	123,773	5,000	10,000	190,000	28,000	75,000	110,500	
Number of potential shares	123,773	5,000	10,000	190,000	28,000	75,000	110,500	542,273

- **Stock options (OSAs) valid at 31 December 2018**

General Meeting	30/06/2017		11/04/2018	Total
	Stock options/Subscription warrants		Stock options	
Type of authorised instruments				
Total authorised quantity	100,000		350,000	450,000
Term of the authorisation	38 months		38 months	

Management Board or General Meeting grant date	17/07/2017	11/04/2018	13/06/2018	
Number of options allocated	28,000	36,270	5,000	69,270
Type of Instrument	Stock options	Stock options	Stock options	
Financial year starting points	18/04/2017	11/04/2018	13/06/2018	
Term of validity	10 years	10 years	10 years	
Exercise price	€11.00	€14.00	€14.00	
Exercised at	0	0	0	
Expired	-28,000	0	0	-28,000
Valid at	0	36,270	5,000	
Number of potential shares	0	36,270	5,000	41,270

- **Free stock options valid at 31 December 2018**

General Meeting	11/04/2018
	Allocations of Free Shares (AGAs)
Type of authorised instruments	
Total authorised quantity	100,000
Term of the authorisation	38 months

Management Board or General Meeting grant date	11/04/2018
Total number of Free Shares allocated	25,415

Type of Instrument	Allocations of Free Shares (AGAs)
Financial year starting points	11/04/2018
Term of validity	10 years
Exercise price	€0.00
Exercised at	0
Expired	0
Valid at	25,415
Number of potential shares	25,415

11. PROVISIONS AND DEPRECIATION IN THE BALANCE SHEET

	Provision start of year	Provisions for the year	Reversals for the year	Provisions end of year
Provisions for disputes	77	0	0	77
Provisions for foreign exchange losses	2	1	2	1
GRAND TOTAL	79	1	2	78
Exploitation	77	0	0	77
Financial	2	1	2	1
Exceptional				

A provision of €77 k relating to the risk of penalties arising from social security contributions was recorded in 2017.

12. CONVERTIBLE BOND LOANS

As at 30 June 2017, the Company had issued a convertible bond of a maximum amount of €7.1 million . Following the Company's listing on the Euronext regulated market on 30 May 2018, on 31 May 2018, the Board of Directors recorded the automatic conversion of all of the convertible bonds issued by the Company into ordinary shares and the corresponding capital increase. The 71,000,000 convertible bonds₂₀₁₇ were automatically converted into 615,577 ordinary shares.

13. MISCELLANEOUS INTEREST BEARING LOANS AND BORROWINGS

The residual amount of €170 k from the Coface prospecting advance was fully repaid during the first half of 2018.

The advances made at the end of 2018 consist of the zero-rate loan taken out with Bpifrance on 24 June 2014 for innovation aid. This loan, with a nominal amount of €850 k, is repayable over five years and the first repayment took place on 06/01/2016. The residual debt at the end of 2018 amounted to €298 k.

On 11 April 2018, the Board of Directors issued a convertible bond loan in the amount of €7 million, subscribed for by the Kreos Company with drawdown in tranches. The repayment period is 36 months, and the contractual interest rate is 11%. Only tranche A was issued as at 31 December 2018 in the amount of €4 million.

The loan is combined with the issue of 70,000 share subscription warrants (BSAs) which may be exercised in proportion to the drawdowns of the bond debt and allocated in the amount of €1 providing access to ordinary shares at an exercise price of €11 per share.

At 31 December 2018, no subscription warrants were exercised and the residual amount of the loan was €3,580 k.

14. STATEMENT OF RECEIVABLES AND BORROWINGS

Statement of receivables	Gross amount	Repayment less than one year	Repayment more than one year
Receivables from fixed assets			
Other investments	1	0	1
Receivables from equity interests	1,893	443	1,450
Security deposits	211	0	211
Receivables from current assets			
Trade and other receivables	1,001	1,001	0
Group trade receivables	443	443	0
Other receivables	4,029	4,029	0
Expenses to spread over several years	82	35	47
Prepaid expenses	280	280	0
TOTAL	7,939	6,231	1,708

Statement of debt	Gross amount	Repayment less than one year	Repayment more than one year
Zero-rate loan for innovation	298	128	170
Sub-total conditional advances	298	128	170
Convertible bond loans and accrued interest not due	3,580	1,483	2,097
Loans and borrowings from credit institutions	0	0	0
Miscellaneous interest-bearing loans and borrowings	0	0	0
Accounts payable and related accounts	1,913	1,913	0
Group accounts payable	1,050	1,050	0
Tax and social security debts	2,015	2,015	0
Other debts	76	76	0
Deferred income	369	67	302
Sub-total debts	9,003	6,605	2,398
TOTAL	9,300	6,732	2,568

15. DETAIL OF ACCRUED INCOME

ACCRUED INCOME	Amount
INVOICES TO BE ISSUED	122
Invoices to be issued Voluntis Inc.	443
Credit note to be received	12
TOTAL	577

16. DETAIL OF EXPENSES TO PAY

Expenses to pay	Amount
Invoices not received	822
Invoices not received - Voluntis Inc.	1,050
Provision of paid leave	429
“RTT” provision (for days in lieu)	22
Holiday bonuses provision	56
Variable compensation and premiums provisions	351
Social/paid leave expenses provisions	214
Social expenses/RTT (days in lieu) provisions	11
Social expenses/holiday bonuses	28
Social expenses/premiums	176
State: expenses to pay	189
TOTAL	3,348

17. DETAIL OF DEFERRED INCOME

	Operating income	Financial income	Exceptional income
Deferred income	369		
TOTAL	369	0	0

18. DETAIL OF PREPAID EXPENSES

	Operating expenses	Financial expenses	Extraordinary expenses
Prepaid expenses	280		
TOTAL	280	0	0

19. ELEMENTS CONCERNING RELATED COMPANIES

Balance sheet entries	31/12/2018	31/12/2017
<i>Equity interests</i>	1	1
<i>Receivables from equity interests</i>	1,893	1,302
<i>Trade and other receivables</i>	443	164
<i>Provision of equity interests</i>	-1	-1
<i>Provisions for foreign exchange risk</i>	0	-2
<i>Accounts payable and related accounts</i>	-1,050	-456

Foreign exchange differences - liabilities	56	2
Credit amounts are negatively signed		

Entries in profit and loss statements	31/12/2018	31/12/2017
Operating income	425	459
Provision reversal for impairment of equity investments	2	0
Provision reversal for foreign exchange risk		
Financial proceeds on advances	34	28
Provision for impairment of receivables		
Operating expenses	-4,244	-3,001

Debtor amounts are negatively signed

20. NET REVENUE

Revenue	France	Foreign	TOTAL
Licences	500		500
Service provisions	1,436	2,126	3,562
Subscriptions, Maintenance and Royalties	0	0	0
Intra-group invoices		425	425
TOTAL	1,936	2,551	4,487

21. DETAIL OF EXCEPTIONAL INCOME

A breach of customer contract indemnity has been recognised for €300 k.

22. DETAIL OF EXCEPTIONAL EXPENSES

Extraordinary expenses mainly consist of the net book value of assets sold for €3.5 k.

23. BREAKDOWN OF TAX ON PROFITS

	Before tax	Corresponding tax	After tax
+ Current income	-15,986	0	-15,986
+ Exceptional income	297	0	297
+ 2018 research and innovation tax credit	0	1,790	1,790
- foreign tax charge withheld at source	0	0	0
- Employee profit sharing	0	0	0
Accounting income	-15,690	1,790	-13,899

Research Tax Credit (RTC)

The Company has increased its research and development efforts, resulting in a further increase in R&D expenses compared to the previous year and a research tax credit (RTC) recorded in the 2018 expenses of €1,790 k, compared to €1,683 k in 2017.

Competitiveness and employment tax credit (CICE):

The tax credit for competitiveness and employment was recognised for an amount of €55 k in 2018, compared to €54 k for 2017. The CICE supported the Company's R&D investment policy by increasing the workforce dedicated to this activity.

These credits can be repaid the following year, given that Voluntis is still an SME as per the EU definition.

24. TABLE OF SUBSIDIARIES AND INVESTMENTS

Voluntis draws up consolidated financial statements. The key figures of its US subsidiary Voluntis Inc. are as follows:

SUBSIDIARIES & HOLDINGS (in € thousands)	Capital	Reserves and retained earnings	Percentage of capital held in %	Book value of securities held		Loans and advances granted	Revenue	Profit/(loss) (of the last financial year)	Dividend
A. Details of holdings (whose inventory value exceeds 1% of the Company's capital)	In €	In € thousands		Gross In €	Net In €	In € thousands	In € thousands	In € thousands	In € thousand s
1 - Subsidiaries (more than 50% of the capital held by the Company)									
Voluntis Inc.	873	-1,080	100	873	39	1,080		191	0
2 - Holdings (10 to 50% of the capital held by the Company)									
B. Aggregate information regarding other subsidiaries and holdings									
1 - Subsidiaries not included in (A) a) French b) Foreign									
2 - Holdings not included in (A) a) French b) Foreign									

Exchange rate used for conversion €/USD: Average rate: 1.1384 Closing rate: 1.1450

25. FINANCIAL COMMITMENTS

Commitments given:

A first demand guarantee was granted to the lessor of the principal establishment for the amount of €211 k. This guarantee is counter-guaranteed to the benefit of the issuing bank in the form of a cash bond totalling €104k.

To guarantee the Kreos Bonds, the Company granted Kreos a collateral pledge on some of its assets (particularly its receivables, bank accounts, and intellectual property rights).

Commitments received

Kreos has committed to subscribe for bonds issued by the Company for an additional amount of €3 million (€1.5 million for each additional tranche), subject to certain conditions.

Reciprocal commitments

Non applicable.

26. INCREASE AND REDUCTION OF FUTURE TAX DEBT

At year-end, the amount of the increases and reductions of the future tax debt can be analysed as follows:

INCREASE IN FUTURE TAX DEBT

31/12/2018

Foreign exchange differences - assets	2
Foreign exchange differences - liabilities	58
Provisions for foreign exchange losses	1
Share of non-deductible current account interest	91
Share of non-deductible directors' fees	302
TOTAL	454

REDUCTIONS IN FUTURE TAX DEBT

	31/12/2018
Foreign exchange differences - liabilities	1
2018 Financial year	55
Research tax credit	1,790
TOTAL	1,846

<i>Depreciation deemed deferred</i>	0
<i>Losses subject to indefinite carry forward</i>	56,377
<i>Long-term capital losses</i>	0

27. AVERAGE WORKFORCE

The average economic workforce (FTE) is as follows:

Employees by category	2018	2017
Engineers and managers	89	89
Employees and technicians	1	2
TOTAL	90	91

28. RELATED PARTIES

The Company has not entered into significant transactions under abnormal market conditions with related parties.

The zero-rate innovation loan agreement signed with Bpifrance Financement in 2014 is considered to have been granted to the Company under normal conditions compared to the usual criteria for the award of this type of financing by Bpifrance Financement.

29. COMPENSATION OF SENIOR EXECUTIVES

The Company changed its mode of governance on 11 April 2018, from a French société anonyme with a management board and supervisory board to a French société anonyme with a Board of Directors.

For the 2018 financial year, the amount of gross compensation received by the Company's administrative and management bodies (members of the Supervisory and the Management Boards until 11 April 2018, then members of the Board of Directors and Management Board thereafter) amounted to €1,447,225.

28.2 Statutory Auditors' report on financial statements prepared according to French accounting standards for the financial year ended 31 December 2018

RBB BUSINESS ADVISORS

ERNST & YOUNG et Autres

Voluntis

Exercice clos le 31 décembre 2018

Rapport des commissaires aux comptes sur les comptes annuels

RBB BUSINESS ADVISORS
113 bis, rue de l'Université
75007 Paris
S.A. au capital de € 150.000
414 202 341 R.C.S. Paris

Commissaire aux Comptes
Membre de la compagnie
régionale de Paris

ERNST & YOUNG et Autres
Tour First
TSA 14444
92037 Paris-La Défense cedex
S.A.S. à capital variable
438 476 913 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

Voluntis

Exercice clos le 31 décembre 2018

Rapport des commissaires aux comptes sur les comptes annuels

A l'Assemblée Générale de la société Voluntis,

Opinion

En exécution de la mission qui nous a été confiée par vos assemblées générales, nous avons effectué l'audit des comptes annuels de la société Voluntis relatifs à l'exercice clos le 31 décembre 2018, tels qu'ils sont joints au présent rapport.

Nous certifions que les comptes annuels sont, au regard des règles et principes comptables français, réguliers et sincères et donnent une image fidèle du résultat des opérations de l'exercice écoulé ainsi que de la situation financière et du patrimoine de la société à la fin de cet exercice.

L'opinion formulée ci-dessus est cohérente avec le contenu de notre rapport au comité d'audit.

Fondement de l'opinion

■ Référentiel d'audit

Nous avons effectué notre audit selon les normes d'exercice professionnel applicables en France. Nous estimons que les éléments que nous avons collectés sont suffisants et appropriés pour fonder notre opinion.

Les responsabilités qui nous incombent en vertu de ces normes sont indiquées dans la partie « Responsabilités des commissaires aux comptes relatives à l'audit des comptes annuels » du présent rapport.

■ Indépendance

Nous avons réalisé notre mission d'audit dans le respect des règles d'indépendance qui nous sont applicables, sur la période du 1^{er} janvier 2018 à la date d'émission de notre rapport, et notamment nous

n'avons pas fourni de services interdits par l'article 5, paragraphe 1, du règlement (UE) n° 537/2014 ou par le Code de déontologie de la profession de commissaire aux comptes.

Justification des appréciations - Points clés de l'audit

En application des dispositions des articles L. 823-9 et R. 823-7 du Code de commerce relatives à la justification de nos appréciations, nous portons à votre connaissance les points clés de l'audit relatifs aux risques d'anomalies significatives qui, selon notre jugement professionnel, ont été les plus importants pour l'audit des comptes annuels de l'exercice, ainsi que les réponses que nous avons apportées face à ces risques.

Les appréciations ainsi portées s'inscrivent dans le contexte de l'audit des comptes annuels pris dans leur ensemble et de la formation de notre opinion exprimée ci-avant. Nous n'exprimons pas d'opinion sur des éléments de ces comptes annuels pris isolément.

■ Reconnaissance du chiffre d'affaires

Risque identifié	Notre réponse
Le paragraphe 3.15 « Constatation du chiffre d'affaires » de l'annexe aux comptes annuels présente les principes de reconnaissance du chiffre d'affaires sur les ventes de produits et services. En effet, le chiffre d'affaires de votre société a différentes sources, telles que l'octroi de licences, la réalisation de prestations de services (développement spécifiques, intégration, assistance), la fourniture d'abonnements et de maintenance, la perception de redevances (<i>royalties</i>) et vise des accords de collaboration et de distribution. Le chiffre d'affaires sur les ventes de produits et services est généralement comptabilisé lorsque les risques et les avantages inhérents à la propriété ont été transférés à l'acheteur. Mais les modalités de reconnaissance du chiffre d'affaires peuvent différer selon la nature du produit ou du service vendu. Ainsi, par exemple, lorsque les prestations de services impliquent une modification substantielle du logiciel licencié ou présentent un degré de complexité supérieur aux projets habituellement réalisés et susceptible d'entraîner des risques particuliers quant à leur achèvement, le chiffre d'affaires de la licence est reconnu selon l'avancement des prestations de services. De plus, votre société peut conclure des accords comprenant plusieurs obligations combinées. Nous avons donc considéré que la reconnaissance du chiffre d'affaires constitue un point clé de l'audit en raison de la multiplicité des sources de chiffre d'affaires, parfois combinées dans un même contrat, de la multiplicité des modalités de reconnaissance du chiffre d'affaires en découlant, et celles-ci faisant parfois appel au jugement de la direction.	▶ Nos travaux ont principalement consisté à : ▶ prendre connaissance du processus mis en place au sein de votre société pour recenser et analyser les contrats clients ; ▶ examiner les éléments préparés par la direction, tels que les analyses de contrats préparées par la direction financière ; ▶ réaliser des tests, par sondages, afin de rapprocher les montants comptabilisés des éléments sous-jacents (informations contractuelles, avenants, factures, état d'avancement, etc.) ; ▶ examiner le traitement comptable et l'information financière donnée en annexe aux comptes annuels au regard de ces éléments de fond et des principes comptables applicables ; ▶ vérifier les formules de calcul utilisées.

■ Frais de développement

Risque identifié	Notre réponse
Comme indiqué dans la note 3.1 « Frais de recherche et développement » de l'annexe aux comptes annuels, les frais de développement de logiciels sont comptabilisés en immobilisations si les critères suivants sont remplis : ▶ le projet, nettement individualisé, a de sérieuses chances de réussite technique et de rentabilité commerciale ; ▶ votre société a la volonté d'achever, de mettre sur le marché et de supporter durablement le logiciel concerné ; ▶ votre société sait évaluer de façon fiable les dépenses attribuables à l'immobilisation incorporelle au cours de son développement. La valeur nette comptable des actifs incorporels relatifs aux frais de développement immobilisés s'élève à M€ 2,9 et celle des développements à immobiliser en cours à M€ 0,8 au 31 décembre 2018. Les logiciels créés sont amortis sur la durée d'utilité de l'actif. La durée d'utilité est estimée de manière individuelle pour chaque logiciel. La date de début d'amortissement est définie par la survenance de l'un des événements suivants : ▶ signature du D.O. (<i>Design Output</i>) pour les produits déjà commercialisés et justifiant des autorisations réglementaires pour la version considérée ; ▶ à partir de l'obtention de la première autorisation ; ▶ constatation du premier euro de chiffre d'affaires. Nous avons considéré que l'évaluation des actifs incorporels relatifs aux frais de développement est un point clé de l'audit en raison de leur importance significative dans les comptes annuels de votre société et des hypothèses nécessaires pour déterminer leur caractère activable et amortissable.	Nos procédures d'audit ont notamment consisté à prendre connaissance de l'évaluation et des éléments justifiant les hypothèses clés utilisées par la direction en particulier dans la détermination des durées d'utilité et sur le respect des critères d'activation. Nous avons notamment effectué les travaux suivants : ▶ prise de connaissance du processus de contrôle interne de suivi des frais de développement par entretiens avec la direction financière et le département Recherche et Développement ; ▶ analyse de l'évolution des projets de développement ; ▶ réalisation de procédures analytiques afin d'apprécier la cohérence de l'évolution des montants comptabilisés, avec l'avancement des projets de développement dans leur ensemble et les heures engagées par projet ; ▶ réalisation de contrôles arithmétiques sur le fichier de suivi des frais de développement ; ▶ réalisation de tests, par sondages, afin de rapprocher les montants activés avec des pièces justificatives (D.O., autorisations réglementaires, contrats clients, business plans, etc.).

Vérifications spécifiques

Nous avons également procédé, conformément aux normes d'exercice professionnel applicables en France, aux vérifications spécifiques prévues par les textes légaux et réglementaires.

■ **Informations données dans le rapport de gestion et dans les autres documents sur la situation financière et les comptes annuels adressés aux actionnaires**

Nous n'avons pas d'observation à formuler sur la sincérité et la concordance avec les comptes annuels des informations données dans le rapport de gestion du conseil d'administration et dans les autres documents sur la situation financière et les comptes annuels adressés aux actionnaires.

Nous attestons de la sincérité et de la concordance avec les comptes annuels des informations relatives aux délais de paiement mentionnées à l'article [D. 441-4](#) du Code de commerce.

■ **Rapport sur le gouvernement d'entreprise**

Nous attestons de l'existence, dans le rapport du conseil de surveillance sur le gouvernement d'entreprise, des informations requises par les articles L. 225-37-3 et L. 225-37-4 du Code de commerce.

Concernant les informations fournies en application des dispositions de l'article L. 225-37-3 du Code de commerce sur les rémunérations et avantages versés aux mandataires sociaux ainsi que sur les engagements consentis en leur faveur, nous avons vérifié leur concordance avec les comptes ou avec les données ayant servi à l'établissement de ces comptes et, le cas échéant, avec les éléments recueillis par votre société auprès des sociétés contrôlant votre société ou contrôlées par elle. Sur la base de ces travaux, nous attestons l'exactitude et la sincérité de ces informations.

■ **Autres informations**

En application de la loi, nous nous sommes assurés que les diverses informations relatives à l'identité des détenteurs du capital ou des droits de vote vous ont été communiquées dans le rapport de gestion.

Informations résultant d'autres obligations légales et réglementaires

■ Désignation des commissaires aux comptes

Nous avons été nommés commissaires aux comptes de la société Voluntis par votre assemblée générale du 9 mai 2018 pour le cabinet RBB BUSINESS ADVISORS et du 25 juin 2008 pour le cabinet ERNST & YOUNG et Autres.

Au 31 décembre 2018, le cabinet RBB BUSINESS ADVISORS était dans la première année de sa mission sans interruption et le cabinet ERNST & YOUNG et Autres dans la onzième année (dont une année depuis que les titres de la société ont été admis aux négociations sur un marché réglementé).

Responsabilités de la direction et des personnes constituant le gouvernement d'entreprise relatives aux comptes annuels

Il appartient à la direction d'établir des comptes annuels présentant une image fidèle conformément aux règles et principes comptables français ainsi que de mettre en place le contrôle interne qu'elle estime nécessaire à l'établissement de comptes annuels ne comportant pas d'anomalies significatives, que celles-ci proviennent de fraudes ou résultent d'erreurs.

Lors de l'établissement des comptes annuels, il incombe à la direction d'évaluer la capacité de la société à poursuivre son exploitation, de présenter dans ces comptes, le cas échéant, les informations nécessaires relatives à la continuité d'exploitation et d'appliquer la convention comptable de continuité d'exploitation, sauf s'il est prévu de liquider la société ou de cesser son activité.

Il incombe au comité d'audit de suivre le processus d'élaboration de l'information financière et de suivre l'efficacité des systèmes de contrôle interne et de gestion des risques, ainsi que le cas échéant de l'audit interne, en ce qui concerne les procédures relatives à l'élaboration et au traitement de l'information comptable et financière.

Les comptes annuels ont été arrêtés par le conseil d'administration.

Responsabilités des commissaires aux comptes relatives à l'audit des comptes annuels

■ Objectif et démarche d'audit

Il nous appartient d'établir un rapport sur les comptes annuels. Notre objectif est d'obtenir l'assurance raisonnable que les comptes annuels pris dans leur ensemble ne comportent pas d'anomalies significatives. L'assurance raisonnable correspond à un niveau élevé d'assurance, sans toutefois garantir qu'un audit réalisé conformément aux normes d'exercice professionnel permet de systématiquement détecter toute anomalie significative. Les anomalies peuvent provenir de fraudes ou résulter d'erreurs et sont considérées comme significatives lorsque l'on peut raisonnablement s'attendre à ce qu'elles puissent, prises individuellement ou en cumulé, influencer les décisions économiques que les utilisateurs des comptes prennent en se fondant sur ceux-ci.

Comme précisé par l'article L. 823-10-1 du Code de commerce, notre mission de certification des comptes ne consiste pas à garantir la viabilité ou la qualité de la gestion de votre société.

Dans le cadre d'un audit réalisé conformément aux normes d'exercice professionnel applicables en France, le commissaire aux comptes exerce son jugement professionnel tout au long de cet audit. En outre :

- ▶ il identifie et évalue les risques que les comptes annuels comportent des anomalies significatives, que celles-ci proviennent de fraudes ou résultent d'erreurs, définit et met en œuvre des procédures d'audit face à ces risques, et recueille des éléments qu'il estime suffisants et appropriés pour fonder son opinion. Le risque de non-détection d'une anomalie significative provenant d'une fraude est plus élevé que celui d'une anomalie significative résultant d'une erreur, car la fraude peut impliquer la collusion, la falsification, les omissions volontaires, les fausses déclarations ou le contournement du contrôle interne ;
- ▶ il prend connaissance du contrôle interne pertinent pour l'audit afin de définir des procédures d'audit appropriées en la circonstance, et non dans le but d'exprimer une opinion sur l'efficacité du contrôle interne ;
- ▶ il apprécie le caractère approprié des méthodes comptables retenues et le caractère raisonnable des estimations comptables faites par la direction, ainsi que les informations les concernant fournies dans les comptes annuels ;
- ▶ il apprécie le caractère approprié de l'application par la direction de la convention comptable de continuité d'exploitation et, selon les éléments collectés, l'existence ou non d'une incertitude significative liée à des événements ou à des circonstances susceptibles de mettre en cause la capacité de la société à poursuivre son exploitation. Cette appréciation s'appuie sur les éléments collectés jusqu'à la date de son rapport, étant toutefois rappelé que des circonstances ou événements ultérieurs pourraient mettre en cause la continuité d'exploitation. S'il conclut à l'existence d'une incertitude significative, il attire l'attention des lecteurs de son rapport sur les informations fournies dans les comptes annuels au sujet de cette incertitude ou, si ces informations ne sont pas fournies ou ne sont pas pertinentes, il formule une certification avec réserve ou un refus de certifier ;
- ▶ il apprécie la présentation d'ensemble des comptes annuels et évalue si les comptes annuels reflètent les opérations et événements sous-jacents de manière à en donner une image fidèle.

■ Rapport au comité d'audit

Nous remettons au comité d'audit un rapport qui présente notamment l'étendue des travaux d'audit et le programme de travail mis en œuvre, ainsi que les conclusions découlant de nos travaux. Nous portons également à sa connaissance, le cas échéant, les faiblesses significatives du contrôle interne que nous avons identifiées pour ce qui concerne les procédures relatives à l'élaboration et au traitement de l'information comptable et financière.

Parmi les éléments communiqués dans le rapport au comité d'audit figurent les risques d'anomalies significatives, que nous jugeons avoir été les plus importants pour l'audit des comptes annuels de l'exercice et qui constituent de ce fait les points clés de l'audit, qu'il nous appartient de décrire dans le présent rapport.

Nous fournissons également au comité d'audit la déclaration prévue par l'article 6 du règlement (UE) n° 537-2014 confirmant notre indépendance, au sens des règles applicables en France telles qu'elles sont fixées notamment par les articles L. 822-10 à L. 822-14 du Code de commerce et dans le Code de déontologie de la profession de commissaire aux comptes. Le cas échéant, nous nous entretenons avec le comité d'audit des risques pesant sur notre indépendance et des mesures de sauvegarde appliquées.

Paris et Paris-La Défense, le 21 mars 2019

Les Commissaires aux Comptes

RBB BUSINESS ADVISORS

ERNST & YOUNG et Autres

Jean-Baptiste Bonnefoux

Franck Sebag