



FOR IMMEDIATE RELEASE

VOLUNTIS REPORTS BUSINESS REVIEW AND FINANCIAL RESULTS FOR FIRST HALF OF 2019

Fundamental and Promising Advances for the Commercialization of Voluntis Digital Therapies

- **Oncology:** U.S. Marketing Authorization for Oleena™, the first digital therapeutic in oncology (post-closing of the period)
- **Diabetes:** CE marking of Insulia version supporting NPH/isophane insulin
- **Commercialization:** Start of commercialization of Voluntis digital therapies leveraging the new U.S. reimbursement framework for remote patient monitoring (post-closing of the period)
- **Capabilities:** Expansion of the Theraxium platform with enhanced data analytics and implementation of a new customer service platform
- **Commercial organization:** Strengthening of the sales team following the recruitment of Berkley Nelson as Chief Growth Officer

*Conference call today at 3:30pm cest: to access please see details
at the end of the press release*

CAMBRIDGE, Mass., and PARIS, France – September 19, 2019, 08:00am CEST - Voluntis (Euronext Paris, Ticker: VTX - ISIN: FR0004183960), a leader in digital therapeutics, today released its first half of 2019 financial results and business highlights.

"The first half of 2019 marks the achievement of strategic milestones of our roadmap: the strengthening of our portfolio, particularly with Oleena™ in oncology, and the start of the commercialization of Insulia leveraging the new national reimbursement framework in the U.S.," said Pierre Leurent, CEO of Voluntis. "Voluntis keeps reinforcing its highly differentiated profile in the digital therapeutic space based on its end-to-end DTx platform and its extensive portfolio of solutions. We are confident about the prospects for the coming six months, which should see the expansion of our collaborations with Biopharma leaders as well as the recording of the first revenues from the direct commercialization of our solutions in the U.S."

The fundamental advances of the first half of the year: strengthening of the product portfolio, start of the commercialization leveraging a new reimbursement framework, extension of the technological platform's capabilities and successful structuring of the organization



ONCOLOGY: Obtaining marketing authorization for Oleena™, the first digital therapy in oncology (event occurring after the end of the period)

Voluntis has received a marketing authorization from the FDA for Oleena™, as a Class II medical device, for use in all oncology indications. Oleena™ is a digital therapeutic, based on web and mobile technologies, that allows cancer patients to manage their symptoms independently and to be monitored remotely by healthcare teams throughout their treatment. Once the Oleena™ solution is prescribed by the healthcare team, patients are guided in real time by personalized information, recommending what they should know and do at all times.

In the United States, 15 million people live with cancer and 90% of them experience symptoms related to their condition, which can lead to unscheduled hospitalization. It is estimated that up to \$25 billion could be saved annually by reducing unplanned hospitalizations and emergency visits. Symptom management is currently viewed by community practices as a leading opportunity for cost savings and the most popular task performed by advanced practitioners. Digital innovations like Oleena™ represent a breakthrough in the management of symptoms, which is a cornerstone of oncology practice.

DIABETES: Obtaining CE marking to add NPH insulin to Insulia

Insulia is the first digital therapy with European regulatory approval to provide automated titration recommendations for all types of basal insulin, including Neutral Protamine Hagedorn (NPH) insulin and all first and second generation long-acting basal insulin analogues.

This extended version of Insulia is available in the United Kingdom and Germany, where Voluntis has launched pilot programs. In the United States, where the rising cost of insulin has become a major public health issue, Voluntis has filed a 510(k) premarket notification and is currently working to answer the questions raised by the FDA.

COMMERCIALIZATION: Start of commercialization of Voluntis digital therapies leveraging the new US reimbursement framework for Remote Patient Monitoring (event occurring after the end of the period)

Voluntis has started executing a new contracting approach, based on signing agreements with healthcare professionals leveraging the new CPT codes 99453, 99454 and 99457 established by CMS on January 1st, 2019.

Voluntis considers this evolution of the reimbursement landscape as being a strong catalyst to the growth of its diabetes business, and estimates that most of its target users in the field of diabetes are managed by a payer covering the new codes.

CAPABILITIES: Extension of the technological capabilities

The Theraxium platform, which is the backbone of Voluntis digital therapeutics, has been continuously upgraded. The emphasis has been placed on advancing the data analytics capabilities in order to manage larger and various data sets and transform them into actionable insights.

CAPABILITIES: Expansion of the commercial capabilities

The recruitment of Berkley Nelson as Chief Growth Officer and member of the Leadership Team is part of Voluntis' growth strategy. Berkley's expertise in implementing payor strategies and provider solutions, acquired in major medical device and service companies, will be pivotal to deliver on the revenue growth. The commercial organization is growing with the addition of new positions and will soon be supported by a comprehensive service platform, Voluntis Practice Solutions, designed to support at scale healthcare professionals' adoption and billing under the new reimbursement framework.



On-track to execute the roadmap to 2021

In oncology, the marketing authorization of Oleena™ was a major milestone, delivered according to the plan disclosed in May 2018 for the initial public offering. This event paved the way to the introduction of digital therapeutics in oncology, while triggering rising interest from Biopharma leaders. Upgraded versions of Oleena™ are already under development.

In diabetes, the implementation of Voluntis Practice Solutions will sustain the commercial rollout of Insulia in the USA. The FDA clearance of Insulia supporting NPH is prioritized over the FDA clearance of Voluntis' solution for diabetes patients treated with basal-bolus therapy. The results of the Telesage clinical trial, sponsored by Sanofi to assess the medico-economic impact of Diabeo, are now expected to be released in H1 2020.

2019 Half Year Results

In the first half of 2019, Voluntis generated revenue of €2.0 million compared with €2.2 million for the same period in 2018. The Group is still in a transition phase towards a turnover that consists more of recurring revenues related to the marketing of its products than of pre-launch revenues related to product development and approval. While direct sales to payers and providers did not contribute to revenues in the first half of 2019, the Group is continuing active negotiations to sign contracts with these key players.

During the first half of 2019, the Group finalised its investment strategy in the United States and Europe, in line with its deployment ambitions. This has resulted in the strengthening of the commercial structure and technological capabilities of the Theraxium platform, in order to support the marketing and deployment of Insulia® and Oleena™ in strategic regions. Cost control and the optimal resource allocation strategy kept operating expenses under control at €10.8m, stable compared to the first half of 2018.

EBITDA was € -6.6 million and operating income was € -8.0 million in the first half year 2019.

At the end of June 2019, Voluntis' available cash position amounted to €14.2 million compared to €19.8 million at 31 December 2018.

About Voluntis

Voluntis creates digital therapeutics that empower people suffering from chronic conditions to self- manage their treatment every day, thus improving real-world outcomes. Combining mobile and web apps, Voluntis' solutions deliver personalized recommendations to the patient and the care team so that they can, for example, adjust treatment dosage, manage side effects or monitor symptoms. These real- time recommendations are based on digitized clinical algorithms. Leveraging its Theraxium technology platform, Voluntis has designed and operates multiple digital therapeutics, especially in diabetes and oncology. Voluntis has long-standing partnerships with leading life science companies. Based out of Boston and Paris, France, Voluntis is a founding member of the Digital Therapeutics Alliance. For more information, please visit: <http://www.voluntis.com>.

Voluntis is traded on the Euronext Paris – Compartment C market

Ticker: VTX – ISIN: FR0004183960

Voluntis will host a conference call in English on September 19 at 3:30pm CEST.

To participate in the conference call, please select your number from the list below:



France: +33 1 70 71 01 59

International: +44 20 71 94 37 59

Conference code: 18303259#

***The [presentation](#) will be made available just before the start of the call.*

**** A replay will be available via:*

France: +33 (0)1 70 71 01 60

UK +44 20 3364 5147

Conference code: 418874422#

Contacts

Voluntis

Matthieu Plessis

Chief Financial Officer

investors@voluntis.com

+33 (0)1 41 38 39 20

NewCap

Investor relations

Louis-Victor Delouvrier

voluntis@newcap.eu

+33 (0)1 44 71 94 94

NewCap

Media relations

Nicolas Merigeau

voluntis@newcap.eu

+33 (0)1 44 71 94 98

Appendix

Consolidated Income Statement

€m	Actuals as of June 30	
	2019	2018
Revenue	2.0	2.2
Other operating revenue	0.5	0.4
Total operating revenue	2.5	2.6
Personnel expenses	(6.5)	(6.7)
Other operating costs	(2.7)	(3.0)
Depreciation, amortisation & operating provisions	(1.3)	(0.9)
Operating income	(8.0)	(7.9)
Financial income	(0.5)	(0.2)
Income tax	0.0	0.0
Net income	(8.4)	(8.1)
EBITDA	(6.6)	(7.0)

Simplified cash flow statement

€m	Actuals as of June 30	
	2019	2018
Net cash flows from/(used in) operating activities	(6.9)	(6.7)
Net cash flows from/(used in) investing activities	(0.5)	(0.9)
Net cash flows from/(used in) financing activities	1.9	34.3
CASH FLOW VARIANCE	(5.6)	26.8
Net foreign exchange difference	0.0	0.0
OPENING CASH BALANCE	19.8	1.8
CLOSING CASH BALANCE	14.2	28.6

Simplified Financial situation

€m	Actuals as of	
	30/06/2019	31/12/2018
Assets		
Intangible assets	1.8	1.9
Tangible assets	3.8	0.6
Financial non-current assets	0.3	0.3
Other non-current assets	0.6	1.0
Non current assets	6.4	3.7
Receivables	1.1	1.5
Other current financial assets	-	0.1
Other current assets	4.8	5.4
Cash on hand	14.2	19.8
Current assets	20.2	26.8
Total	26.6	30.6

€m	Actuals as of	
	30/06/2019	31/12/2018
Liabilities		
<i>Shareholder equity</i>	<i>9.1</i>	<i>17.3</i>
Financial debt (non current)	6.0	2.2
LT provisions and other non current liabilities	2.2	3.4
Non current liabilities	8.2	5.6
Financial debt (current)	2.9	1.4
Payables and other current liabilities	6.3	6.2
Current liabilities	9.3	7.6
Total	26.6	30.6