



Eugene Consulting Inc.
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Report on Voluntis

About the Company

- Voluntis creates digital therapeutics that empower people with chronic conditions to self-manage their treatment every day
 - Their solutions combines mobile and web apps, use clinical algorithms to deliver personalized recommendations to patients and their care teams
 - They design and operate multiple digital therapeutics, especially in oncology and diabetes
 - These digital therapeutics accompany and enhance a specific medication or medical device
- Their vision: the advancement of information technologies will help to resolve certain healthcare system issues, notably related to chronic disease expansion
- They design digital therapeutics that transform healthcare by:
 - Designing integrated care services
 - Aligning the interests of patients, providers and payers
 - Driving costs down while improving quality
 - Establishing a collaborative relationship between patients and their doctors
- They have long-standing partnerships with leading life science companies such as AstraZeneca, Microsoft
- The company is based in Cambridge, MA and Paris, France and was founded in 2001
- Executives:
 - Chairman: Eric S Elliott
 - CEO/Founder: Pierre Leurent
 - CFO: Guillaume Floch
 - CTO/Founder: Etienne Vial
 - Chief Medical Officer: Genevieve D'Orsay
 - Chief Business Office/Founder: Romain Marmot
 - Chief Growth Officer: Berkley C Nelson
- Board Members:
 - Eric S Elliott (Voluntis SA)
 - Franck Noiret (Innovation Capital SASU)
 - Dr Jan Berger
 - Pierre Laurent (Voluntis SA)
 - Laurent Higuere
 - Viviane Monges
- They are a founding member of the Digital Therapeutics Alliance <https://dtxalliance.org>
- They have raised a total funding of \$31.6M
- Investors:
 - Debiopharm Innovation Fund
 - Innovation Capital - lead investor
 - Bpifrance - lead investor
 - Qualcomm Ventures



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- Karista
- Sham
- Cr dit Mutuel Innovation
- The company went public on Mar 30, 2018
 - Their valuation at IPO was \$120M, raised €30.1M at IPO

Products and Services

- Voluntis' digital therapeutic apps accompanies existing medication or medical devices
 - The aim to monitor side effects, guide symptom management, promote protocol adherence, recommend dosage or connect patients with their healthcare teams
- In the diabetes m-health field, their digital therapeutic solution is the most extensively studied on the market
- Voluntis' quality management system complies with requirements from the major, global regulatory agencies, with particular emphasis on the US and EU regulation
- Since 2010, their quality systems and processes have been ISO 9001 certified for global quality processes and ISO 13485 for medical device quality systems
- All validation engineers are certified by the ISTQB, the International Software Testing Qualifications Board

Theraxium Platform

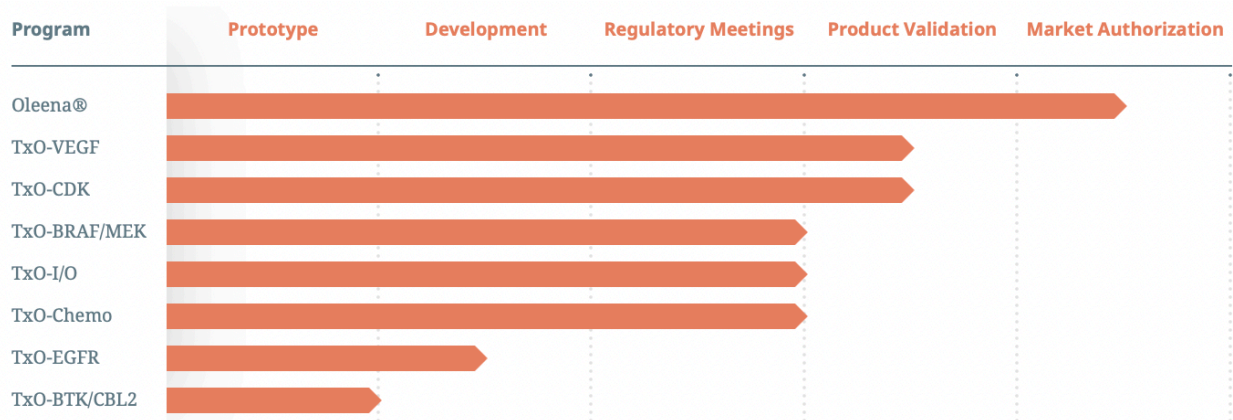


- A comprehensive and highly flexible platform that transforms health data into medical intelligence for better care
 - It enables healthcare organizations to monitor patients remotely, support patient assistance programs, track adverse events and prompt compliance
- Theraxium is the underlying platform that supports all digital therapeutics developed by Voluntis in the field of cancer treatment
- Its technology embeds specific modules to design and simulate algorithms
 - Medical rules are coded in domain specific language with a high level of granularity to reflect temporality and contextualization
 - Voluntis has leveraged these modules to design an off-the-self library of clinical algorithms, which can be furthered customized
 - It integrated modules with predefined UX templates and configurable workflows
- The platform offers a scalable architecture to develop a full suite of solution
- Operated on the Cloud, Theraxium is a model web-based and mobile platform that can
 - Collect data
 - Host data
 - Process communication flows
 - Analyze data
 - Automate effective recall
- Theraxium Oncology was developed after 4 years of research and development in partnership with patients, life science partners and cancer institutes



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- Theraxium has been implemented in 50+ programs covering more than 20 therapeutic fields
- 6 out of 10 top pharmaceutical leaders have deployed Theraxium
- It has provided support and monitoring to over 610,000 patients in 12 countries
- Theraxium has been used as a backbone for a pipeline of oncology digital therapeutics



Software Project Delivery Expertise

- The Voluntis teams has developed a unique expertise in developing software medical devices
- Voluntis project managers ensure that clients' projects fully meet their expectations, timeline and budget throughout design, development, validation and delivery phases
 - They also address all tips specific to medical device manufacturing with Voluntis' experts



- It is their proprietary digital therapeutic that enables patients to self-manage symptoms across a wide range of cancer therapies and allows care teams to remotely monitor patients
- It is the first FDA Class II Software-as-a-Medical Device to be marketed for use across all cancer indications
 - Oleena is able o support patients across a wide range of cancer types and anticancer treatments
- Oleena is the first digital therapeutic obtaining market authorization in oncology and it is powered by Theraxium Oncology
- Oleena provides patients with personalized insights to self-manage the symptoms they experience over the course of their disease
 - Symptoms such as diarrhea, pain, nausea and vomiting



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- Using embedded evidence-based clinical algorithms, Oleena delivers automated recommendations to patients in real-time
 - Recommendations in clued personalized coaching for symptom management as well as on-demand directions for initiation and dose of supportive therapies based on the patients' individual care plan
- It focuses on:
 - Self-management of symptoms
 - Evidence-based algorithms and qualifying questions within Oleena evaluate each symptom reported in order to give personalized recommendations
 - Personalized dosing of medication
 - Guidance for self-monitoring of relevant health indicators
 - Patients have access to detailed information and resources within the app
 - Oleena continues monitoring the patient until the symptom subsides and adapts the recommendations according to how the symptom evolves
 - Identifying the need for escalation of care
 - When security is too high for self-management, Oleena connects the patients to the care team
- Healthcare teams get access to automated and adaptive insights on patients' symptoms in order to support patients wherever and whenever
 - Each time a patient enters data, Oleena saves it to a detailed history file, providing an easy way for providers to understand the patients' current status and symptom evolution
- Oleena comes with a full set of supporting services
 - Data analysis - using data to improve supportive care strategies and patient experience
 - Patient onboarding - get patients familiar with Oleena and provide ongoing engagement support
 - Practice implementation - seamlessly integrate Oleena with existing workflows
 - Customer success - support practice productivity goals and maximize the potential of Oleena

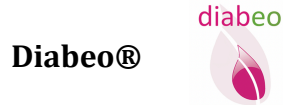


- Insulia provides automated basal insulin dose recommendations and coaching messages for people with type 2 diabetes while enabling the health care team to remotely monitor progress
- Healthcare practitioners prescribe Insulia using their dedicated web portal and set up the treatment plan rules that will adjust basal insulin dosing based on the patients' specific needs
 - The user then receives an activation code to get started with their personalized app
- The app uses blood glucose readings and any hypo symptoms to recommend doses in real-time



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- Clinical algorithms built into the application help to calculate this
- This data is shared with the health care team
- This enables providers to deliver tailored telemedicine services



- Diabeo is a digital solution for type 1 and type 2 diabetes patients treated on a basal-bolus insulin regimen
- It provides therapeutic and decision-making support for effective diabetes management to help adult patients dose their basal and bolus insulin, facilitate interactions between patients and their healthcare professionals, support remote management and the implementation of telemedicine services
 - It suggests insulin dosage, through algorithmic calculations that are specific to the patient and based on their particular doses.
- It is a regulated healthcare product that was granted a CE Mark in 2013
- It is not approved for use in the U.S.
- Daibeo is a registered trademark of Sanofi

eCO (e-Cediranib Olaparib)

- eCO application was designed for patient self-reporting and management of hypertension and diarrhea using remote monitoring
- AstraZeneca selected Theraxium Oncology to design a digital therapeutic that supports women undergoing treatment for ovarian cancer
- In 2016, in collaboration with AstraZeneca and the US National Cancer Institute, it was assessed as a digital therapeutic for women undergoing treatment for recurrent platinum-sensitive high-grade ovarian cancer in clinical trial of cediranib in combination with olaparib
 - Hypertension and diarrhea events reported via the eCO app allowed rapid response and positive overall patient experience.
 - Patients provided positive responses on the use of the eCO app
 - Feelings of being more uncoiled in their care and better connected with their healthcare team

Developments in 2020

November 23, 2020 - Voluntis completes a capital increase of €5.9 Million

- Voluntis announced the completion of a capital increase without preferential subscription rights exclusively reserved to the category of investors defined below for a total amount of €5.9 million.
- The securities were subscribed by investors specialized in the healthcare sector, including Debiopharm Innovation Fund, Corporate fund of Swiss company Debiopharm, and Indigo,



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the holding company of M. Eric Carreel, Chairman & co-founder of Withings, which strengthened its position

- The issue price of the new shares was set at €4.43 per share
- The net proceeds of the capital increase (€5.7 million) will be used by Voluntis to strengthen its financial resources, in particular to develop its commercial activities with the pharmaceutical industry and to contribute to the financing of R&D activities
- This capital raising complements the financing tools already in place, notably the €2 million state-guaranteed loan (PGE) and the recently obtained €1 million R&D Innovation loan, and enables the Company to cover its financing needs beyond the next 12 months

November 16, 2020 - Voluntis receives CE mark for Oleena

- This is a key milestone that paves the way to the future commercialization of its digital therapeutics for oncology in the EU
- They have now receiving marketing authorization to commercialize Oleena in both the US and the EU
- It marks the 12th regulatory clearance obtained by Voluntis for a proprietary digital therapeutic

November 12, 2020 - Voluntis extends its digital therapeutics cloud infrastructure worldwide with Microsoft

- Voluntis announced that its cloud infrastructure supporting its Theraxium Platform will migrate to Microsoft Azure
- This new cloud infrastructure provides the global reach that Voluntis and its partners need to operate and support digital therapeutics in a growing number of countries
- With this new cloud infrastructure, Voluntis' technical operations costs are also more closely aligned with the actual volume of end-users worldwide - this will improve the profitability of digital therapeutics deployed by industry partners
- The new platform also offers expanded technological capabilities
 - The Azure solution can enrich the set of functionalities of the Theraxium platform

October 29, 2020 - Voluntis and Redox enter into a new partnership

- Voluntis and Redox entered into a strategic partnership to work together in an effort to improve the integration of digital therapeutics as part of routine clinical practice and enrich EHR data with actionable insights on how patients experience their treatment at home
- The partnership will allow providers to automate and adapt insights on their patients' treatment journey within their Electronic Health Records
- The 2 companies will integrate Voluntis' digital therapeutics platform, Theraxium, with Redox' interoperability platform
- Through this partnership, the Voluntis portfolio of products are interoperable with any organization using Redox for healthcare data exchange
 - Currently, more than 900 healthcare organizations using 55EHR vendors trust Redox to digitally integrate digital health solutions into their operations



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Recent Strategic roadmap announced on March 4, 2020

- The company announced a strategic prioritization of the oncology business
- In regard to diabetes, they are suspending investments links to direct commercialization in the U.S.
 - Profitability horizon proves to be too distant in view of the Group's objective of financial break-even
 - These investments represent approximately 15% of the Group's operating expenses
 - They have decided to postpone the additional developments required by the FDA's feedbacks on the version of Isulia adapted to insulin NPH during the process of application of this product in the U.S.
 - Instead, they aim to execute new commercial partnerships that can fully exploit the potential of Voluntis' diabetes solutions
- In regards to Insulia, the scope of the global distribution contract with Sanofi has been refocused on the French territory only
 - This is in line with Sanofi's new strategic directions in diabetes
- The partnership related to Diabeo, a solution developed with Sanofi France and CERITD, will end in December 2020
- They expressed that a primary focus on the oncology business, the renewal of the partnership approach in diabetes and the adaptation of the cost structure are the key levers of Voluntis' path to profitable growth
- Voluntis recently formed 2 new partnerships, with Novartis and Bristol-Myers Squibb, related to its Theraxium Oncology platform
 - They are also in discussion with several other pharmaceutical companies to improve patients' experience with any types of cancer treatments
 - These collaborations will generate upfront payment and will have a significant contribution to Voluntis Group's revenues as of 2020
- They plan to make Oleena available to several cancer centers in the U.S. in the first half of 2020 to generate new real-world data and reinforce its experience with integration into clinical workflows
- In view of the priority allocation of resources to oncology and the projected operating loss for the 2019 financial year, which is of a similar order of magnitude to 2018, the Group is contemplating the implementation of a significant cost reduction plan in order to achieve its objective of financial break-even in 2021
- Voluntis confirms its objective of financial break-even (EBITDA) in 2021, for invoiced revenues in 2021 ranging between Euro 8 and 12 million and an annual cost base of the same order, following the prioritization of the oncology business and the adaptation of the cost structure



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Developments in 2021

March 30, 2021 - They announced that 2020 Annual results are in line with their strategic roadmap announced in March 2020

- Voluntis announced they are on track on all key indicators, including, conclusion of agreements, new milestone partnerships and improvement of results due to the optimization of their cost structure
 - Their commitment to establishing major partnerships with leading pharmaceutical companies to commercialize their digital therapeutics, with priority on oncology, led to the collaboration with Bristol-Myers Squibb and Biocon Biologics
 - The global licensing agreement with Biocon Biologics in diabetes is based on Insulia®
 - Voluntis now has a total of 10 digital therapeutics co-developed and/or commercialized with pharmaceutical partners
- Due to these large-scale partnerships, sales invoicing have increased 3.8 times compared to 2019
 - They reached € 10.2 million in fiscal year 2020
- The increase in cash flow linked to partnerships and the strategic reduction in the cost structure have led to a very significant improvement in free cash flow, which stands at € -2.1 million in 2020

March 18, 2021 - Broward Health and Voluntis launch a new clinical evaluation program on digital therapeutics for metastatic breast cancer

- Voluntis announced a collaboration with Board Health
- The partnership will focus on conducting a real-world evaluation of Oleena®
 - Oleena will be provided to patients with HR_/HER2- metastatic breast cancer to support them in self-managing symptoms and side effects of their conditions and treatments
 - The clinical research will start enrolling patients in 2021, following an initial deployment of Oleena at Broward Health North
 - They will evaluate how a prescribed digital therapeutic application can support remote symptom management for patients with cancer
- In preparation for the clinical evaluation, during the design phase, specific attention was paid to optimizing the user experience, answering health literacy challenges and supporting multiple language

March 4, 20201 - Voluntis strengthens its global customer support services in collaboration with Zenedesk

- Voluntis announced the upgrade of its global customer support infrastructure in collaboration with customer service software company Zendesk
- Voluntis will leverage Zendesk's capabilities to integrate and streamline the support services it provides for its Pharma partners as part of the commercialization of co-developed digital therapeutics and in full compliance with applicable regulations



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February 15, 2021 - Voluntis announces issuance of European patent for drug dosing support with its Theraxium digital therapeutic platform

- Voluntis announced the issuance of a new patent by the European Patent Office (EPO) for intelligent patient support in drug dosing applied in the field of diabetes for insulin titration support
 - The algorithms developed by Voluntis will automatically recommend to a patient, day by day and according to the evolution of their monitoring data, a progressive increase of the dose to bring the patient into the target range as specified by their physician
 - Once the target range is reached, the dose will then remain stable as long as the patient's follow-up data stays within the target range
 - Safety mechanisms are also present to decrease the dose if the situation requires it
- In the field of diabetes, the patent obtained relates to the optimization of insulin titration, based on the evolution of fasting blood glucose levels over several days to recommend to the patient an appropriate dose of basal insulin to be injected, in accordance with their treatment plan