

Semler Scientific Inc

(SMLR)

Summary (2022)

- [PAD \(Peripheral Artery Disease\)](#) is a major problem for health which increases the risk 40%-70% of all-cause mortality and morbidity and is usually undetected. [A self checklist – Take Your Socks Off.](#)
- QuantaFlo is designed to address and serve the area of underdiagnosed and undertreated PAD (Peripheral Artery Disease).
- QuantaFlo which can be operated by healthcare aid in a physician office provides an easy and convenient alternative to standard ABI (Ankle Brachial Index) Doppler Test which must be done by technician usually in a specialty clinic.
- From product perspective, Semler Scientific has no advantage over competitors, it is expected that competitors with digital PAD devices to enter the market. Also, Semler Scientific has ONLY ONE product in market.
- Generally, Semler Scientific's product is not approved for reimbursement under any third-parties payor (HMOs, insurers...) code.
- Primary competitive products to QuantaFlo are ABI blood pressure cuff test which is the gold standard for PAD test.
- Semler Scientific sells to and works through health insurance plans and risk-assessment companies as customers and implementation partners. Also company operates software as a service (SaaS) model.
- Low stock compensation.

Business

- As of 2021/03/13, Semler had a sales and marketing team of 70 persons and employee 124, employee 86 in 2020.
- 2021/04 company entered an agreement with Mellitus Health Inc to market and distribute Insulin Insights, a software product that recommends insulin dose for

diabetic patients in the United States. Before this agreement, the company made a minority investment to this private company on 10/2020.

- 2020/10 company made an investment in a private company whose product, Discern, is a test for early Alzheimer's disease.
- QuantaFlo is cleared by FDA through 501(k) clearance pathway **but not PMA** (pre-market approval) which the approval process requires proof of the ***SAFETY and EFFECTIVENESS for its intended use*** of the device and to be supported by extensive data, technical information, preclinical and clinical trials
-
- Company offers a license model for QuantaFlo services in two ways: 1. Fixed-fee service which provides a fixed price in a fixed period (monthly or annual) regardless how many tests are provided to patients. 2. Variable-fee service which fee is charged per use. As of 12/31/2021, 59% of the company's customers are in the fixed-fee license model and 41% of customers are in variable-fee license model.
- Company has a largest customer who accounted for 40.8% of revenue in 2021 and 47.2% of revenue in 2020.
- Semler Scientific serves customers such as insurance plans, physician groups and risk assessment groups.
- Company uses SaaS model to generate revenue, thus the cost of sale consist of
 - Depreciation expense of vascular testing products for lease
 - The write-off of residual value of retired testing products
 - The cost of manufacturing hardware and personnel and other miscellaneous items
- Company is able to grow business by expanding customer networks, insurance plans, providing services to more primary care providers and adding more products and services.
- In the short term, the company expects to incur an increase in operating expense due to the wage inflation.
-

Notes

- CEO Doug Murphy-Chutorian M.D. had minor stroke after a surgery in 2019.
- In 2011, Semler began commercializing a first generation system to aid in diagnosis of peripheral arterial diseases.
- In 2015, QuantaFlo was first patented and approved by FDA in 2015.
- In 2016, Company increased the installation of QuantaFlo. Moreover, the company migrated customers to QuantaFlo from its lower-margin older product.

Also, the company moved away from operating the WellChec platform and instead, contracted with home risk assessment companies for using QuantaFlo to have lower financial risk and lower expenses. (20170310)

-
- [According Statista.com, there are over 50 million of U.S. population are over 65 years of age.](#)
- [There are an estimated 238 million people living with PAD world-wide, and they are underdiagnosed and undertreated. Also, General public awareness of PAD is very low according American College of Cardiology.](#)
- [Although PAD has a significant impact on patient's health, patients and healthcare providers have not paid enough attention to this disease. The situation may be due to few factors \(a study published in American Heart Association Journal\):](#)
 - o Lack of ease diagnose tools;
 - o Limited availability of the first-line diagnostic test, the ankle-brachial index, in clinics;
 - o Incorrect perceptions that a leg vascular disease is not fatal and that the diagnosis of PAD would not necessarily change clinical practice.
- [Results show a positive screening of previous undetected PAD was independently associated with short term and long term increased risks for mortality and MACE \(major adverse cardiovascular events\)](#) - The report was provided by Semler Scientific. [This research report was peer-reviewed and published in Journal of Vascular Surgery.](#) QuantaFlo was used in this research to diagnose PAD.
- [FDA issued a substantial equivalence determination for QuantaFlo and did not require approval of PMA \(premarket approval application\)](#) on 03/05/2015.
- Clinical results have shown that alternative ABI (Automated ABI) have concordance of above 90% comparing to Doppler ABI (traditional way). **Readers should aware that Semler Scientific's FloChec was used in this study.**
<https://pubmed.ncbi.nlm.nih.gov/24103216/>
<https://ir.semilerscientific.com/news-releases/news-release-details/clinical-study-using-quantaflor-published-peer-reviewed-journal>
-
-
- QuantaFlo
 - o Sensitivity – 86%
 - o Specificity – 100%
 - o Accuracy – 87.5%
- **Rival products –**
 - o [Dopplex® ABILITY, DA100PB, an automated IAB device; Huntleigh Healthcare, Cardiff, UK. This link contain a research report that conducts PAD diagnosis using DA100PB to detect PAD and the result:](#)

- Sensitivity of ankle brachial index was 79%
 - Specificity was 91%
 - Overall accuracy was 88%
- **FlowMet-R**; Medtronic, Santa Rosa, California. This link contains a research report in which FlowMet-R was used to diagnose PAD.
 - Please copy this link and paste to URL
<https://www.sciencedirect.com/science/article/pii/S1051044320307727>
 - Sensitivity – 89%
 - Specificity – 74%
- Company signed an agreement with #a company to market and distribute a new product line. With the agreement, the company purchased \$1.2 million of product but was unable to generate significant revenue. Company was allowed to sell the product within one year upon agreement termination. Semler Scientific decided to give up and write off \$1.2 million.
- Company has tried to sell licensed products from two companies in 2020 and 2021, but the progress has been slow or failed. (Question to company. Is the company preparing to acquire a company or just marketing and distributing products? What is the goal the company is trying to achieve?)
- Company has a concentrated customer base. The sales from two largest customers account for 40.8% and 28.6% of the company's revenue in 2021, 47.2% and 22.8% in 2020. Moreover, three customers accounted for 21.9%, 20.1%, 16.6% of the company's account receivable, and four customers accounted for 31.2%, 19.4%, 15.7%, and 10.4% in 2020.
- The strategic sales to healthcare insurers instead of healthcare providers give Semler Scientific a marketing advantage.
 - Avoid the laborious marketing to each clinician and expenses.
 - Advantages that insurers will promote Semler Scientific products to healthcare providers if insurers find the preventive products can reduce medical expense now and in the future.
 - Utilize the insurers' networks.
-
- **DISCERN (SYNAPS Dx – SDx)** – A device for diagnostics of neurodegenerative disorder and condition. Many insurers are not paying PLA codes and the codes may or may not be FDA approved.
-
- Semler has a revenue-recurring model: 1. Monthly fixed fee; 2. Monthly variable fee or fee per test which is based on usage.