

Miniaturized Surgical Measurement and Navigation Systems

EXECUTIVE SUMMARY OF THE BUSINESS PLAN

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Miniaturized measurement and navigation system
CLIPON (prototype I)

Naviswiss' miniaturized surgical measuring and navigation system CLIPON

- *Shortens operation time*
- *Improves the outcome*
- *Allows for immediate quality control*
- *Reduces risks of implant revisions*

Thus they help to reduce health care costs and improve the quality of the operational outcome for the patient.

Executive Summary of the Business Plan

The increasing life expectancy of the population, and with it greater mobility in old age and higher demands on the quality of life, are having a noticeable influence on modern developments in medicine. At the same time there is increasing pressure to cut down costs in the health services and to comply with increasingly stringent regulatory and legal requirements.

Physicians nowadays are obliged to deal with the conflicting claims of various stakeholders and at the same time have to fulfill their primary task, i.e. of ensuring the well-being of their patients. Furthermore, the digital era also is making increasing inroads into the medical field, assisting physicians in this task.

These include opportunities

- a) for supporting the operative process by an economic, efficient and user-friendly method of measuring the exact position and alignment of implants,
- b) for accompanying the surgeon in the handling of instruments with the aid of navigation (similar to the GPS system in cars), and
- c) for documenting the surgical steps made in this way as a form of quality control.

Although navigation systems have already been available in the medical market for over 20 years, they have tended generally to be cumbersome in use, ergonomically inadequate and expensive. More especially, they forced the physician to adapt their workflow to the navigation system rather than vice versa.

The market for cost-efficient and effective measuring and navigation systems for various orthopaedic application amounts to approx. CHF 350 million. Applications in soft tissue surgery would make it much greater still.

Naviswiss has set itself the priority aim of developing a cost-efficient, user-friendly solution, which satisfies the demands and expectations of the various stakeholders. Naviswiss was founded in 2007 for the purpose of concentrating and refining the know-how accumulated by the product developer IFE (Industrielle Forschung und Entwicklung GmbH) in the field of surgical navigation and measuring systems. Starting out from the navigation system developed between 1995 and 2000 for the then Swiss Stratec Medical, Naviswiss developed the hand-held measuring and navigation system LOCAS. For this purpose a total of CHF 2.5 million was made available to Naviswiss by various investors.

In addition a family of patents was filed.

Activities aiming at miniaturization – with all the necessary easy handling and ergonomic advantages – are now to be systematically pursued with the planned development and launching of CLIPON. The operator support given by CLIPON will be of advantage for both physicians and patients and will serve to enhance quality. At the same time CLIPON will provide a documentation of the surgical procedure as a protection against legal claims, and will help enormously to reduce costs by shortening the time needed for operations.

Numerous discussions have taken place with acknowledged specialists in this field, who have confirmed considerable interest in CLIPON and have offered their support with the clinical testing of the CLIPON system. Negotiations are currently ongoing with leading manufacturers of medical implants and equipment with a view to a strategic partnership in clinical testing and in marketing.

As a first step, Naviswiss intends to concentrate on the important field of hip replacement, followed by applications in knee replacement, replacements of other joints, maxillary surgery, and in the field of spinal surgery.

Income is expected to be earned through sales of the basic system (hardware) to the strategic partners, the disposables (markers and sterilization covers), the application specific software modules, and service contracts. The major share (>40%) will come from the disposables. Break-even should be reached in year 3; the sales target in year 6 after financing of the first tranche is CHF 35 million plus an EBITDA of 40%:



The LOCAS prototype of Naviswiss



The CLIPON prototype of Naviswiss

in CHF	Year 1 (2012)	Year 2 (2013)	Year 3 (2014)	Year 4 (2015)	Year 5 (2016)	Year 6 (2017)
Net Revenue:						
CLIPON units		485'000	2'968'200	5'602'720	8'257'125	9'816'400
Disposables (Markers + Sterilization Covers)		192'938	1'566'653	4'956'388	10'239'491	16'075'826
Application Software		122'500	766'850	2'280'950	6'049'442	8'882'524
Service revenue & Services Income			306'000	577'600	851'250	1'012'000
TOTAL NET REVENUE		800'438	5'607'703	13'417'658	25'397'308	35'786'750
EBITDA		-1'099'081	-1'607'458	1'504'260	5'397'580	11'250'397
<i>EBITDA margin</i>				40%	44%	40%
NET PROFIT (LOSS)		-359'946	-438'658	1'930'533	4'459'783	7'421'313
FREE CASH FLOW		-1'150'393	-1'942'265	674'570	4'920'474	7'735'779
PERSONNEL (in FTE)		3	7	14	32	56
					56	85

For the final product development and market launch of CLIPON, Naviswiss is seeking a total of CHF 3.3 million from interested investors, with a first tranche of CHF 1.0 million being needed up to production of the pre-serial product for clinical testing.

Private or finance investors will be sought as investors for the first tranche. The resources for the second tranche could be made available either by the same investors or by strategic partners.

With the development of the LOCAS prototype, Naviswiss has proved that the new technological approach fulfills the criteria for precision and the necessary functionality. Thus the technical risk involved by scaling down to the miniaturized CLIPON can be rated as marginal.

As possible exits with an attractive value enhancement potential we envisage a trade sale to a strategic partner, a fusion with another med tech company (possibly in combination with an initial public offering), or a management buyout.