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Diagnostics for premature births popular with investors

What mechanisms trigger a birth? Several blind spots still exist in our knowledge of gynaecology and obstetrics, but one of these gaps is now closer to being addressed: how to reliably diagnose a premature birth. The medical device produced by Pregnolia AG in Zurich (Switzerland) measures cervical stiffness and aims to address this gap. The ETH Zurich spin-off has just successfully raised its second round of funding.

The Swiss Pregnolia AG specialises in the early diagnosis of premature birth. In modern obstetrics, premature births give rise to high annual costs for medical treatment and care. Premature birth is also responsible for poorer health outcomes of the children. If nothing else, premature births, which mostly cannot be predicted by experienced gynaecologists, are a source of uncertainty and frustration to specialists.

The ETH biomechanical engineer and founder of Pregnolia, Dr Sabrina Badir, met her co-founder, Dr Francisco Delgado, a Massachusetts Institute of Technology (MIT) graduate, at a start-up speed dating event at the ETH Zurich. The Pregnolia System is based on a ground-breaking application of a novel concept: cervical stiffness as a bioindicator for premature birth. Early data from clinical trials demonstrate that cervical stiffness provides more accurate prediction of a possible premature birth than measuring cervical length. The Pregnolia System is a reliable and user-friendly device that measures cervical stiffness with a handheld probe using negative pressure. The softer the tissue, the higher the likelihood of a premature birth. Data are currently being collected on the Pregnolia System in the large-scale clinical trial "Soft Cervix", which will form the basis for diagnosis guidance for practical gynaecological usage.

Dr Sabrina Badir, Founder & CEO, Pregnolia AG

"In spite of the coronavirus crisis, we gained numerous new investors. The funding round that we just concluded allows us to take a big step forward towards becoming the de facto standard in diagnostics for premature births."

Funding secured

Screening for premature births using the Pregnolia system aims to reduce the pressure on gynaecologists and pregnant women and to lower healthcare-related costs. The level of demand for safe diagnostics for premature births is also reflected in how rapidly Pregnolia managed to obtain series A funding. The offering for the announced 4 million Swiss francs was oversubscribed, even in the difficult environment of the coronavirus crisis. Up to a million francs may additionally be secured in the post-round. Half of the funding was covered by new



shareholders and the existing shareholders remain convinced of the success of the Pregnolia system, having further invested in additional shares.

Susanne Schorsch, Investment Manager, Investiere Venture Capital

"Pregnancy monitoring is a billion-dollar market. The aim of the Pregnolia system is to be able to give an immediate recommendation for therapy thanks to its easy handling in the existing clinical workflow and its high diagnostic reliability, thereby providing "peace of mind" to gynaecologists and pregnant women, a strong competitive advantage. The successful round of funding clearly shows investor confidence in the technology."

Pregnolia had already received in 2019 a 1.4 million Swiss francs grant from the EU as part of the Horizon 2020 programme. These funds are being used in the technical optimisation of the system and on production improvements. The EU grant further attests to the support and recognition of the mission and aims of Pregnolia. It allows a reduction in the cost of the product, increasing access for many healthcare systems.

Francisco Delgado, Founder & Head of R&D, Pregnolia AG "My challenge as the Head of Research and Development for our product is to combine high accuracy of measurement with usability, such that the Pregnolia System integrates with routine gynaecological practice, is accepted by the pregnant women and delivers reliable results for diagnosis."

Preparation for the launch

The current Pregnolia System was certified (CE mark) for the measurement of cervical stiffness in 2019. The resources from the series A funding round serve mainly to prepare for the market release of the diagnostic device. The Pregnolia System must obtain a new certification and all measures for the launch must be set in motion. In addition to creating a distribution network, this also includes negotiating test reimbursement by health insurance companies. In parallel, clinical studies are gathering supporting data. Over 4000 measurements have already been made using the Pregnolia System in Switzerland, the majority of which within the "SoftCervix" trial being carried out in numerous University and Cantonal Hospitals.

Dr Gundula Hebisch, Chief of service at the gynaecological clinic, Frauenfeld Cantonal Hospital (Spital Thurgau AG)

«The Pregnolia Probe is the best quantitative examination "finger" I have tried: very easy to use and hardly felt by the women. I believe this project will soon have a major impact on our routine examinations. »



International studies using the Pregnolia system are also ongoing, namely in the USA, led by Prof. Kristin M. Myers (Columbia University, NY). She was the recipient of the Presidential Early Career Award, PECASE, the highest distinction awarded by the US government to exceptional young scientists and engineers. Myers also recently featured in the episode "Childbirth" of the Netflix series "Sex, explained!".

Prof. Kristin M. Myers, Columbia University

"I was introduced to the founder Sabrina Badir when I was invited to sit on her Ph.D. thesis defence committee. She is a fantastic engineer and on top of that, she is very strong at creating a product built based on the most up-to-date pregnancy biomechanical knowledge and that is easy to integrate into the workflow of the end-user."

In 2012, the WHO publication "Born too soon" noted that premature births are on the rise in most countries and are now the second most common cause of mortality in children below the age of five (Source). The Financial Times - backed platform "Sifted" predicts a value of 5 billion USD for the European Femtech market in 2025 and that Pregnolia could play an important role in this field (Source).

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