OssDsign announces strategic shift to become a pure play orthobiologics company

Uppsala, September 26, 2023, 17:31 CEST. OssDsign AB (publ) today announced a strategic shift to focus its operations on the orthobiologics business in the U.S, in order to increase shareholder value. The new strategy means that OssDsign will become a pure play orthobiologics company focusing on the nanosynthetic bone graft OssDsign Catalyst, an off-the-shelf product characterized by high scalability and high gross margins at 90 percent or above. All activities pertaining to the company's patient-specific cranial implant business will be discontinued in a responsible manner by the end of December 2023, resulting in a substantial cost base reduction going forward. As a result, the future capital requirement ahead of becoming cash flow positive will be significantly decreased. Based on the revised strategy, OssDsign's financial target is to reach sales of SEK 150-200 million in the medium-term, at which point the company also expects to become cash flow positive.

The company will provide a strategy update on an investor webcast on September 27 at 11:00 CEST. The webcast can be accessed via the following link http://www.finwire.tv/webcast/ossdsign/strategy-update/ or via the OssDsign website.

OssDsign Catalyst – a highly innovative and differentiated product
OssDsign Catalyst is a nanosynthetic bone graft that stimulates the formation of healthy bone tissue in spinal fusion surgeries. The product was launched in the U.S. in August 2021. The market clearance in the U.S. is based on preclinical results that surpass what is typically seen with other synthetic bone grafts in the most demanding preclinical model for spinal fusion – the Boden model. Recently, the company also announced that OssDsign Catalyst has received clearance for use in interbody cages in spinal surgery from the U.S. Food and Drug Administration (FDA), allowing surgeons to use OssDsign Catalyst on-label in any interbody cage cleared for use with synthetic bone grafts. OssDsign Catalyst is the first synthetic bone graft to be cleared to market for interbody use based on bone graft data alone. In addition, OssDsign continues to accelerate a robust program of gathering clinical evidence for OssDsign Catalyst. In the first in-patient report from an ongoing clinical study, TOP FUSION, evidence of progression to fusion was observed at 3 months post-surgery, and complete spinal fusion was achieved at 6 months. A post-market safety report, published in November 2022, did not record any device-related complaints or device-related adverse events.

"The outstanding commercial performance of our nanosynthetic bone graft OssDsign Catalyst and the recently announced interbody clearance by the FDA establishes OssDsign Catalyst in the exceptional class of synthetic bone grafts and showcases that the potential of the orthobiologics business is of a magnitude which deserves our full focus. The successful entry into the orthobiologics space has transformed the company's revenue growth and increased gross margins by 30 percentage points in less than three years. There is no doubt that the decision to deploy all resources to the orthobiologics business will boost the company's earnings capability and at the same time significantly reduce the need for additional capital injections ahead of reaching cash flow positivity," commented Morten Henneveld, CEO of OssDsign.

Accelerated roll-out of our high-margin product in the world's biggest market
OssDsign will now be focusing solely on the commercialization of OssDsign Catalyst in the U.S., which represents more than 70 percent of the global market for spinal bone grafts and is characterized by large volumes and highly attractive pricing. The targeted market segment for OssDsign Catalyst is valued at USD 1.8 billion, with an annual growth rate of 8 percent. During the last two years, the U.S. has become OssDsign's most important market, comprising approx. 72 percent of global sales as in the second quarter of 2023, a significant increase from approx. 37 percent in 2020. Only two years after its launch, OssDsign Catalyst sales in the U.S. alone are now exceeding the global sales of its cranial implant product, OssDsign Cranial PSI. In the first six months of 2023, sales of OssDsign Catalyst grew by 453 percent compared to the corresponding period last year. The gross margin for OssDsign Catalyst exceeds 90 percent, and the focus on orthobiologics is therefore expected to be highly accretive to gross profitability going forward. This has been evidenced by the strongly increasing development of the company's gross margin from approx. 46 percent in 2020 to approx. 77 percent on a group level in the second quarter of 2023, mainly driven by the launch of OssDsign Catalyst.

New strategy and financial targets
As part of OssDsign's new pure play orthobiologics strategy, the company will focus on four main areas: i) win in the U.S. through increased commercialization activities; ii) drive high value innovation of the orthobiologics technology platform; iii) prove clinical performance in ongoing and future clinical programs; and iv) build scalability across company functions.

OssDsign's pure play orthobiologics strategy focuses on the high growth and high margin business and gross margin is expected to increase as a result of OssDsign Catalyst's 90 percent or above gross margin profile.

Based on the revised strategy, OssDsign's financial target is to reach sales of SEK 150 – 200 million in the medium term, at which point the company expects to become cash flow positive.

Significant cost base reduction
The strategic shift announced today will potentially affect approximately 25 positions in the company and is expected to reduce annual operating expenditures by approximately SEK 30-40 million, leading to an approx. 30 percent improvement in cash flow[1]. One-off restructuring costs are estimated to have a SEK 10–15 million negative cash impact. In addition, there will be other, non-cash, restructuring costs related to the discontinuation of the cranial implant business.

"As an inevitable consequence of the strategic shift, colleagues who have contributed strongly to OssDsign's successful journey will be affected by this decision. I would like to express my sincere gratitude for their hard work and commitment over the last many years," said Morten Henneveld, CEO of OssDsign.

A responsible phase-out of OssDsign Cranial PSI
To avoid potential negative impact on patients and current customers, OssDsign will continue to deliver Cranial PSI for planned surgical procedures during the remainder of 2023, whereafter it will cease all activities in its cranial implant franchise. As a result of the strategic shift, OssDsign expects declining sales of Cranial PSI in the fourth quarter of 2023. OssDsign has explored the interest from third parties for Cranial PSI business and will continue its effort to seek a total or partial sale of its cranial assets.

This information is such that OssDsign AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person[s] set out above, on 26 September 2023, at 17:31 CEST.

[1] On a like for like basis based on reported H1 2023 financials.