

2.1 CEO Statement

Dear Shareholders,

In H1 of 2024 we have delivered record revenues of €136.2 million compared to €43.7 million in the same period last year, the increase is mainly driven by a \$100 million upfront payment from Medtronic related to the expansion of our artificial intelligence partnership. We expect to receive a further \$100 million from Medtronic by the end of 2024 related to services and the development of additional products and features. Revenues related to the sales of our GI products by our partners, increased by 4.3% to €21.4 million. Dermatology revenues increased by 58.5% to €7.4 million as income from Winlevi® continued to grow and our contract manufacturing business grew by 9.3% to €8.9 million.

Our operating profit was €87.0 million and net cashflow from operating activities was €99.2 million.

At the end of June, we had a cash of €133.4 million, we have no debt and held 1.5 million treasury shares with a market value of €109.0 million.

GI Genius™

In January, the FDA approved ColonPRO™, the new version of software for GI Genius™. ColonPRO™ incorporates an enhanced polyp detection algorithm supported by an even more robust data set which is double the size of the previous one. This has resulted in an improvement in the detection capabilities of GI Genius™ including a 9% reduction in false positives. In addition, the system can help to improve efficiency by providing procedural highlights. The GI Genius™ installed base continues to grow and we continue to develop additional features. The next generation GI Genius™ powered by Nvidia IGX has been submitted to the FDA for approval.

Regarding AI Access, following the receipt of significant number of submissions from third parties, we are now moving several of those applications into the integration phase. We will now start the necessary regulatory approval process with a view to bringing them to market. In addition, our Cosmo IMD team are working on the development of additional SaMD (Software as a Medical Device).

Winlevi®

In March, the Australian Therapeutic Goods Administration (TGA) granted regulatory approval for Winlevi®. In Europe the review of the Winlevi® Marketing Authorisation Application, which was submitted to the EMA by Cosmo in October 2023, is ongoing. In addition, applications for approval have been submitted by our partners in 13 additional countries.

In the U.S. almost 1.1 million prescriptions have been written for Winlevi® since launch to the end of June 2024 and Winlevi® continues to be the #1 most prescribed topical branded product for acne in the U.S.

Our GI products and CDMO business continue to deliver a strong performance

Revenues related to the sales of our GI products by our partners which include Lialda®, Mezavant®, Mesavancol®, Cortiment® and Uceris® grew by 4.3% to €21.4 million and revenue from our CDMO business grew by 9.3% to €8.9 million.

Our development pipeline is progressing according to plan

Our Androgenetic Alopecia phase III studies in males for the treatment of androgenetic alopecia are ongoing in the U.S. and in the EU recruitment has commenced.

Our Oncology (cortexolone 17 α -valerate-21-propionate) phase I dose-ranging study in patients with advanced refractory solid tumours is progressing according to plan.

We have completed the development of a new MMX® formulation of colesévelam, intended for the treatment of bile acid diarrhoea, a disease which is estimated to affect about 1% of the Western population and is caused by an excess of bile acids entering the large intestine. We are now drafting protocols and recruiting sites and expect to begin the phase 2 proof of concept study in Q3/Q4 of 2024.

In April, we commenced a phase II Proof of Concept (POC) study of efficacy and safety of a rifamycin enema for the treatment of mild to moderately active distal ulcerative colitis (UC) and proctitis.



Giovanni Di Napoli
Executive Director, CEO

Our operating profit was €87.0 million and net cashflow from operating activities was €99.2 million.

2.1 CEO Statement continued

In the first half of 2024, our revenue was €136.2 million, net operating expenses were €49.2 million and operating profit was €87.0 million.

Both our existing products and products in development are focused on large markets. It is estimated that 70 million colonoscopy procedures, the focus of GI Genius™, are performed worldwide on an annual basis of which based on the existing GI Genius™ global installed base it is estimated that potential exists to impact 2.7 million patients annually. Including colonoscopy, we estimate that 225 million GI endoscopy procedures are performed annually, therefore beyond colonoscopy the potential exists to develop products to aid decision making and improve efficiency.

An estimated 640 million people are affected by acne worldwide, the focus of Winlevi®, and an estimated 2 billion males are males worldwide affected by androgenetic alopecia, the focus of Breezula™ currently in phase 3 trials.

Financial performance and cash generation

In the first half of 2024, our revenue was €136.2 million, net operating expenses were €49.2 million and operating profit was €87.0 million. Net cash inflow from operating activities was €99.2 million compared to €15.5 million in the same period last year. At the end of June we held cash and short term investments of €133.4 million, 1.5 million treasury shares with a market value of €109.0 million and have no debt.

We paid a dividend of €2.00 per share on the 12th of July 2024.

2024 guidance

We confirm our 2024 guidance of revenues in the range of €260 million - €270 million compared to €92.8 million in 2023 and operating profit in the range of €159 million - €169 million compared to €6.1 million in 2023.

Giovanni Di Napoli

CEO

Dublin, Ireland, 23 July 2024