



Cosmo Full-Year Report 2019

Dublin, Ireland – 3 April 2020 – Cosmo Pharmaceuticals N.V. (SIX: COPN) reports Full-Year results for the year ended 31 December 2019.

Following the spread of coronavirus to the majority of countries in the world resulting in lockdowns and measures to contain the pandemic previously unseen Cosmo wishes to highlight the following:

Cosmo, as a pharmaceutical company, is **exempt from business shutdown provisions in Italy.**

Cosmo's production is up and running, drugs are being shipped and all inputs needed for its operations are being received.

Cosmo holds stocks of API, excipients and materials to enable continued production for quite some time even if the regular supply of these materials should be interrupted.

Employees are present at the company's facilities where necessary and policies and procedures are in place to protect their health and welfare. Non-production related personnel are working remotely.

Due to the investments which Cosmo has made over the years its facilities are up-to-date and contain cutting edge technologies which allow manufacturing operations to be run only by a handful of employees.

The Company is strong and has significant cash and equity resources available to withstand this storm.

Cosmo's management is assuming that the coronavirus pandemic will significantly slow down or stop clinical development and/or the FDA activity. Therefore 2020 will be a different year from the one we had envisaged.

As a result of the actions which Cosmo has taken during 2019, management expects that, on the assumption of FDA approval of Byfavo™ in 2020, **Cosmo will be back to operating profit in 2020.**

Financial Highlights Full-Year 2019

- Revenue €62.5 million compared to € 65.6 million in 2018
- Expenses €74.8 million compared to €82.2 million in 2018, the reduction mainly due to reducing the cost associate with our U.S. organisation
- Operating loss of €12.3 million compared with an operating loss of €16.6 million in 2018
- Loss after tax of €24.5 million, including share of our associate Cassiopea loss of €5.1 million, compared with a loss after tax of €18.1 million in 2018
- Cash and liquid investments €268.2 million compared to €375.8 million 2018

Key Events 2019 - Products and Business

- Byfavo™ sub-licensed to Acacia Pharma Group (“Acacia”) in January 2020 for a €10m upfront payment in Acacia shares, Cosmo also made an investment of €10m in Acacia which combined resulted in Cosmo taking a 14.1% stake in Acacia. Cosmo will receive an additional €20m in Acacia shares on approval of Byfavo™ by the FDA and first Byfavo™ sales and up to US\$105m on achievement of Byfavo™ commercial milestones.
- Aemcolo™ licensed to RedHill Biopharma for high twenty percent royalty plus potential regulatory and commercial cash milestones totalling up to US\$100m. Redhill Biopharma American Depositary Shares received as down-payment and together with investment of US\$36.3m made in the company resulting in Cosmo taking a 19.56% stake in the company.
- Aemcolo™ phase II proof of concept study in IBS-D progressed.
- Significant progress made with the FDA in relation to the second Methylene Blue MMX phase III trial design and endpoints. Cosmo has filed the protocol and related statistical analysis plan with the FDA. Cosmo plans to commence the confirmatory phase III trial in H2 subject to acceptance of the protocol by the FDA and subject to normal clinical operations resuming.
- Marketing Authorisation Application for Methylene Blue MMX 200mg tablets filed with the European Medicines Agency.
- Cosmo unveiled its revolutionary artificial intelligence device, GI Genius™, for the detection of lesions during colonoscopy and subsequently entered into a worldwide distribution deal with Medtronic.
- Cosmo entered into a further collaboration agreement with Medtronic in the artificial intelligence field.
- Eleview® distribution agreement entered into with Medtronic for USA, China and South America and subsequently expanded to worldwide agreement with the exception of Canada and Japan.
- Investigational New Drug (IND) for new chemical entity CB-03-10 for new oncologic product accepted by the FDA.
- Byfavo™ NDA accepted by the FDA, review extension with new PDUFA date of 5 July 2020.

- U.S. cost base eliminated delivering significant reduction in operating expenses.
- Health Canada approved Eleview® which will be commercialised by Pharmascience under the existing licence and supply agreement.
- Associate Cassiopea filed its Winlevi™ NDA with the FDA with a PDUFA date of 27 August 2020 set and announced very positive results of Breezula® full phase II clinical trial.
- Repositioning of the Company completed and now back to the original business-to-business model with significant stakes in the equity of the partners.

Key figures

EUR /000	2019	2018
Income statement		
Revenues	62,495	65,617
Cost of sales	(25,053)	(22,058)
Gross profit	37,442	43,559
Other income	753	886
R&D costs	(15,160)	(10,428)
SG&A costs	(35,342)	(50,638)
Net operating expenses	(49,749)	(60,180)
Operating loss	(12,307)	(16,621)
Net financial (expense) / income	(3,933)	4,615
Share of result of associates	(5,064)	(5,453)
Loss before taxes	(21,304)	(17,459)
Loss after taxes for the period	(24,494)	(18,057)

Statement of financial position	2019	2018
Non-current assets	282,795	251,519
Cash and cash equivalents	110,387	210,689
Other current assets	191,978	163,478
Liabilities	191,427	180,832
Equity attributable to owners of the Company	393,733	443,760
Equity ratio (%)	67.3%	71.1%
Shares		
Weighted average number of shares	14,633,299	15,005,414
Earnings per share (in EUR)	(1.669)	(1.200)

The Full-Year Report 2019 with further information was published on 3 April 2020, 07:00 am CET, and is available for download at:

<http://www.cosmopharmaceuticals.com/investor-relations/financial-reports>

Outlook

Alessandro Della Chà, Chief Executive Officer, said: *“During 2019 Cosmo has executed a complex repositioning following the delay of Methylene Blue MMX. After the deals with Medtronic, RedHill and Acacia we are now fully back to our business-to-business model, further de-risking the Company with the selection of different partners for each product or class of products. The current environment is unexpected and challenging but we have worked hard in the past to set our facilities up to the highest standards, to build up our ample cash and equity resources and to advance a fully-fledged pipeline of new products. We therefore expect to be in a favourable position when the situation stabilises, business opportunities will arise and companies will look for solid and reliable partners. For these reasons Cosmo looks to the future with optimism.”*

2020 Financial Outlook

Cosmo provided full year guidance, assuming approval of Byfavo™ by the FDA, of:

- Full year revenues in the range of €52 - €56 million
- Total expenses in the range of €48 - €50 million (of which ESOP €7.2 million and Depreciation & Amortisation €6.4 million)
- Operating profit in the range of €2 - €8 million

Full-Year 2019 results conference call at 10:30 am CET on 3 April 2020

Alessandro Della Chà, CEO and Niall Donnelly, CFO will present the 2019 results and discuss the outlook for 2020. The conference will be held in English.

The dial-in numbers are:

Continental Europe: +41 (0) 58 310 50 00

UK: +44 (0) 207 107 06 13

USA: +1 (1) 613 570 56 13

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company focused in treating selected Gastrointestinal Disorders and Endoscopy. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, Colonic Infections and detection of colonic lesions. Cosmo has also developed medical devices for endoscopy and has recently entered into a partnership with Medtronic for the global distribution of GI Genius™ it's artificial intelligence device for use in colonoscopies and GI procedures. Cosmo has licensed Aemcolo™ to Red Hill Biopharma and is the licensee of Byfavo™ (Remimazolam) for the U.S. for procedural sedation, which it has sub-licensed to Acacia. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

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