

FOCUS AREA: GASTROENTEROLOGY (DIGESTIVE SYSTEM), DERMATOLOGY (SKIN DISORDERS), AND HEALTH TECH (AI-ENHANCED PLATFORM)			
KEY DATA			SIX: COPN
MARKET CAPITALIZATION (CHF MN)	784	PRICE ON 4 AUGUST 2023	45
ENTERPRISE VALUE (CHF MN)	571	RISK-ADJUSTED NPV PER SHARE (CHF)	92
CASH (30 JUNE 2023) (CHF MN)	213	UPSIDE/DOWNSIDE (%)	105%
MONTHLY OPERATING EXPENSE (CHF MN)	4.0	RISK PROFILE	MEDIUM
CASH LIFE	SUSTAINABLE	SUCCESS PROBABILITY LEAD R&D PROJECT	82.5%
BREAK-EVEN (YEAR)	2021	EMPLOYEES	319
FOUNDED (YEAR)	1997	LISTED (YEAR)	2007
KEY PRODUCTS:	STATUS	MAJOR SHAREHOLDERS:	(%)
- GI GENIUS (LESION DETECTION)	LAUNCHED 2019 (EU) 2021 (US)	- COSMO HOLDING S.A.R.L.	35.0
- WINLEVI (ACNE)	LAUNCHED 2021 (US)	- HEINRICH HERZ AG / LOGISTABLE GROUP	8.4
- BREEZULA (HAIR LOSS MEN)	PHASE III POC	- DIEVINI HOPP BIOTECH HOLDING GMBH & CO. KG	3.8
- LIALDA & UCERIS/CORTIMENT (ULCERATIVE COLITIS)	LAUNCHED 2007 2013	- FREE FLOAT (EXCL. COSMO HOLDING S.A.R.L.)	65.0
- ELEVIEW (LESION RESECTION CUSHION)	LAUNCHED 2017	- AVERAGE DAILY VOLUME (3 MONTHS)	10,537
- AEMCOLO/RELAFALK (TRAVELERS' DIARRHEA/IBS-D*)	LAUNCHED I PHASE II (IBS-D)		
- LUMEBLUE (LESION DETECTION)	LAUNCH 2022 (EU) PHASE III (US)		
- BYFAVO (PROCEDURAL SEDATION)	LAUNCHED 2020 (US)		
- CB-01-33 / COLESEVELAM (BILE ACID DIARRHEA)	PHASE II POC (H2 2023)		
UPCOMING CATALYSTS:	DATE	ANALYST(S):	BOB POOLER
- CB-01-33 - START PHASE II POC IN BILE ACID DIARRHEA	H2 2023		BP@VALUATIONLAB.COM
- WINLEVI - LICENSING AGREEMENTS	DURING 2023		+41 79 652 67 68
- WINLEVI - EU FILING	H2 2023		
* IBS-D = IRRITABLE BOWEL SYNDROME - DIARRHEA PREDOMINANT			
ESTIMATES AS OF 7 AUGUST 2023			
SOURCE: VALUATIONLAB ESTIMATES, COSMO PHARMACEUTICALS			

Back to the roots

2023 guidance reiterated – strong Winlevi H2 ahead

Cosmo Pharmaceuticals (Cosmo) is focused on developing therapies for 1) HealthTech, with GI Genius, an artificial intelligence (AI) enhanced platform with the first application in colonoscopy; 2) Dermatology (skin disorders), including Winlevi for acne and Breezula for hair loss (phase III started in June 2023); and 3) Gastroenterology (e.g., colon infections and solutions to reduce the risk of colon cancer) including Lialda/Mezavant and Uceris/Cortiment both for ulcerative colitis; Aemcolo/Relafalk for travelers' diarrhea and IBS-D (phase II completed), Lumeblue, a colonic lesion detection dye; Eleview, a lesion resection cushion; and Byfavo for procedural sedation. Cosmo's revenues are a mix of sales royalties, manufacturing revenue, and milestone payments from its commercialization partners. Additionally, the company participates in the long-term value creation of its equity stakes in RedHill (14.8% stake), PAION (7.3% stake), and Eagle Pharma (0.7% stake). We derive a sum-of-parts risk-adjusted NPV (rNPV) value of CHF 92 per share with an 82.5% success rate for its lead pipeline project Winlevi (only available in the US yet). We consider Cosmo Medium Risk with a strong balance sheet and eight marketed products (GI Genius, Winlevi, Lumeblue, Eleview, Aemcolo/Relafalk, Byfavo, Lialda/Mezavant, and Uceris/Cortiment) contributing to revenues and sustained profitability.

Key catalysts:

- 1) CB-01-33 (colesevelam) start of phase II POC trial in bile acid diarrhea (H2 2023):** forecasts will be included on positive proof-of-concept (POC) trial results.
- 2) Winlevi licensing agreements (during 2023):** to advance Winlevi global sales with new licensing and supply agreements in the ROW – Winlevi upfront and sales milestones expected to contribute strongly to H2 2023 results.
- 3) Winlevi filing for EU approval (H2 2023):** EUR 90 mn peak sales in the EU due to lower pricing than in the US; our rNPV increases by CHF 2/share with a 90% success rate, the average of EU filing (80%) and US launched (100%)

Flash update

H1 2023: FY 2023 guidance maintained - growth products deliver – strong Winlevi H2 expected

On 26 July 2023, Cosmo reported H1 2022 results driven by strong underlying revenue growth of GI Genius, Lialda, Eleview, and Contract manufacturing. Winlevi's royalties were up sharply. However, its manufacturing income dropped due to timing differences in deliveries in H1 2023 and H1 2022. The company decided to fully repay the convertible bonds on 28 November 2023 with cash at hand. FY 2023 guidance was maintained despite the USD currency headwind signaling a strong H2 2023, expected to be boosted by strong upfront and sales milestones from Winlevi with several new commercialization agreements underway.

COSMO		H1 2023 RESULTS IN A NUTSHELL			
(IN EUR MN)	H1 2023	H1 2022	CHANGE (%)	COMMENT	
SELECTED PRODUCTS:					
WINLEVI	4.4	5.5	-20%	ROYALTY INCOME UP +92% TO EUR 2.5 MN OFFSET BY 55% DROP MANUFACTURING INCOME TO EUR 1.9 MN (TO REBOUND IN H2)	
GI GENIUS	8.5	5.4	57%	US ROLLOUT EXPECTED TO ACCELERATE WHILE SUBSCRIPTION REVENUES SHOULD KICK IN THE NEXT FEW YEARS	
LIALDA	16.6	13.0	28%	REBOUND IN GROWTH IN THE US CONTINUES ON STRONG COMPETITIVE PROFILE COMPARED TO CHEAP GENERICS	
UCERIS / CORTIMENT	3.8	4.1	-7%	CORTIMENT INCOME UP +86% TO EUR 2.6 MN OFFSET BY -56% DROP IN UCERIS SALES TO EUR 1.2 MN HIT BY GENERICS	
ELEVIEW	2.1	1.0	110%	MEDTRONIC NOW RESPONSIBLE FOR GLOBAL SALES (EXCEPT CANADA BY PENDOPHARM) - RELAUNCH AFTER PANDEMIC	
CONTRACT MANUFACTURING	8.3	6.0	38%	REVENUE FROM DRUG DEVELOPMENT AND MANUFACTURING ON BEHALF OF THIRD PARTIES	
OTHERS	0.0	6.5	-101%	H1 2022 INCLUDED EUR 8 MN CORTIMENT SALES MILESTONE COMPARED TO EUR 2.9 MN MILESTONES IN H1 2023	
TOTAL REVENUE	43.7	41.5	5%	BOOSTED BY STRONG UNDERLYING REVENUE GROWTH OF GI GENIUS, LIALDA, ELEVIEW & CONTRACT MANUFACTURING	
COGS	-18.9	-17.2	10%	INCREASE IN WORK-IN-PROGRESS INVENTORY AND COSTS IN FINISHED GOODS	
GROSS PROFIT	24.8	24.3	2%		
OTHER INCOME	0.4	1.1	-60%	INCLUDES SETTLEMENT OF LEGAL PROVISIONS, REVERSAL ACCOUNTS PAYABLE NO LONGER DUE, R&D TAX CREDITS	
R&D COSTS	-8.3	-7.6	9%	INCREASED BY CLINICAL TRIAL COSTS FOR INSTANCE FOR BREEZULA WHICH STARTED PHASE III TRIALS IN JULY	
S,G&A COSTS	-9.8	-9.7	2%	TIGHT COST CONTROL TO CONTAIN EXPENSES	
OPERATING PROFIT	7.1	8.1	-12%	SLIGHTLY LOWER ON STRONG REVENUE GROWTH DESPITE WEAKER USD, LOWER MILESTONES AND HIGHER COGS	
NET FINANCIAL INCOME/(EXPENSE)	-3.5	1.0	-452%	LOWER FINANCIAL INCOME DUE SHIFT IN FX MOVEMENT (WEAKER USD) AND NO INTEREST INCOME FROM ACACIA LOAN	
PROFIT/(LOSS) BEFORE TAXES	3.7	9.1	-60%		
TAXES	-2.2	-1.2	83%	HIGHER TAXES AS WINLEVI (CASSIOPEA) PROFITS TAXED IN ITALY, OTHER PROFITS FROM COSMO TAXED IN IRELAND	
NET PROFIT/(LOSS)	1.5	7.9	-81%	NET PROFIT HIT BY LOWER MILESTONES, HIGHER COGS, LOWER FINANCIAL INCOME AND HIGHER TAXES	

SOURCE: COSMO, VALUATIONLAB ESTIMATES

H1 2023 RESULTS:

- **Total revenue** increased by 5% to EUR 43.7 mn (+22% to EUR 40.8 mn excluding milestones) driven by the solid performance of GI Genius (+57%) as well as a rebound in its established portfolio including Lialda (+28%), Eleview (+110%) and contract manufacturing (+38%). Winlevi royalty income was up sharply (+92%), offset by a drop (-55%) in manufacturing income due to timing differences in deliveries in H1 2023 and H1 2022. This is expected to rebound in H2 2023.
- **Milestones** dropped by 64% to EUR 2.9 mn related to an upfront fee of EUR 0.1 mn for Winlevi and EUR 2.8 mn for Lumeblue. In H1 2022, an EUR 8 mn milestone was received from Ferring triggered by the Cortiment achieving cumulative net sales of EUR 100 mn. In H2 2023, Cosmo sees a substantial increase in upfront and sales milestones for Winlevi, boosted by new commercialization agreements worldwide.
- **Operating profit** decreased by 12% to EUR 7.1 mn on lower milestones and higher COGS.
- **Net cash flow from operating activities** increased by 23% to EUR 15.5 mn.
- **Cash and short-term investments (30 June 2023):** amounted to EUR 222 mn, sufficient to fully repay the EUR 175 mn convertible bonds on 28 November 2023.

GROWTH PRODUCTS:

- **GI Genius (AI-enhanced colonoscopy):** revenue increased by 57% to EUR 8.5 mn. The placement of new devices continues to grow strongly in the US, Europe, Canada, Singapore, Australia, and New Zealand, placed in many renowned hospitals and

institutions. Together with Medtronic, an ecosystem was launched to distribute new AI applications (apps) within the GI Genius platform. The current development pipeline for GI Genius includes 7 apps for gastrointestinal (GI) applications with another 3 apps outside GI. Launching these apps will substantially shorten time-to-market and lead to immediate revenues as soon as the app is downloaded. Additionally, the GI Genius platform creates an opportunity in GI applications next to colonoscopy (19 mn procedures in the US), its first application, such as laparoscopy (15 mn procedures), upper endoscopy (6 mn procedures), ERCP (0.5 mn procedures) and non-GI applications such as arthroscopy (4 mn procedures), rhinoscopy (1.6 mn procedures), cystoscopy (1.5 mn procedures), and laryngoscopy (0,7 mn procedures). We have yet to account for these revenues.

- **Winlevi (acne):** revenue decreased by 20% EUR 4.4 mn, affected by timing differences on deliveries in manufacturing income (-55%). Royalty income surged by 92% on strong underlying growth, with more than 670,000 accumulated total prescriptions (TRx) since its launch, with approximately 15,000 unique prescribers representing 88% of total healthcare practitioners in dermatology. In the US, Winlevi continues to be the #1 branded acne prescription product. In June, Canadian marketing authorization was received, with Sun Pharma expecting the first sales in Q4 2023. Additionally, a license agreement for South Korea was signed with Hyundai Pharmaceuticals. Several other agreements are underway, expected to boost upfront milestones substantially in H2 2023.

ESTABLISHED PORTFOLIO:

- **Lialda (ulcerative colitis):** revenue increased by 28% to EUR 16.6 mn due to increased revenue in the EU and Japan. Many users of generics are switching back to branded Lialda, paying out of pocket, citing that the generic does not work.
- **Uceris/Cortiment (ulcerative colitis):** revenue declined by 7% to EUR 3.8 mn. Cortiment revenue was up firmly by 86% to EUR 2.6 mn, offset by a 56% drop in Uceris revenue in the US, hit by generics. In June, Cortiment was approved in Japan, the world's second-largest market for inflammatory bowel disease products, with a launch expected by August 2023.
- **Eleview:** income increased by 110% to EUR 2.1 mn due to an increased number of units sold.
- **Contract manufacturing:** increased by 48% to EUR 8 mn. Cosmo expects steady growth and is shifting to more profitable products.

PIPELINE:

- **Breezula (male hair loss):** In June, the pivotal phase III development for treating androgenic alopecia (hair loss) in men started. Two phase III trials, "SCALP 1" and "SCALP 2" will be conducted in approximately 60 study centers with around 750 male subjects over 18 years of age targeted for each trial. Topline results are expected at the end of 2024 or the beginning of 2025.

- **CB-03-10 (cancer):** the phase I safety trial in patients with advanced refractory solid tumors is ongoing according to plan. US clinical sites have been activated with six patients treated with an excellent safety profile.
- **CB-01-33 / colesevelam (bile acid diarrhea):** the formulation and intellectual property (IP) protections of colesevelam are completed, and the phase II proof-of-concept (POC) trial is expected to start in H2 2023. Upon positive results, we will include forecasts for CB-01-33.

FY 2023 Guidance maintained despite USD currency headwinds

Despite USD currency headwinds, Cosmo confirmed its FY 2023 guidance, signaling a solid H2 2023 with revenue of at least EUR 66.3 mn. Winlevi is expected to have a strong second half, with revenue boosted by upfront and sales milestones with several commercialization agreements underway. For FY 2023, Total revenue is expected to range between EUR 110 mn (+8%) to EUR 120 mn (+18%). Operating profit is growth guided to range between EUR 25 (-11%) and EUR 35 mn (+25%).

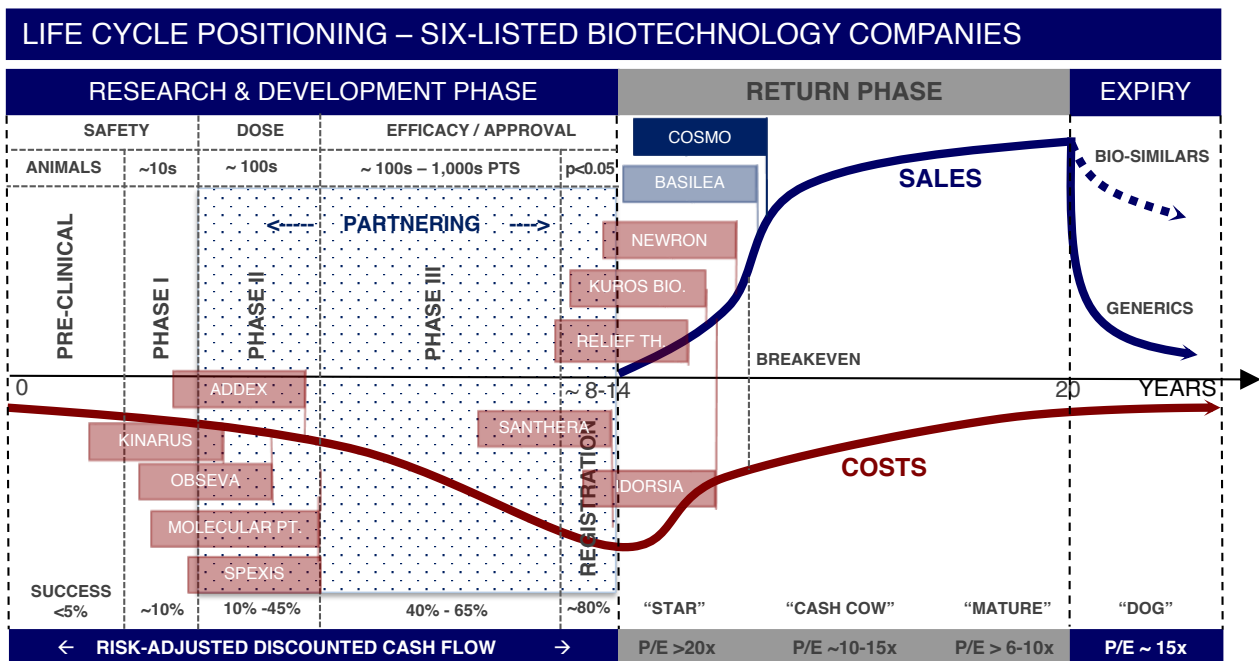
Investment Case, Strategy & Cash

Investment case in a nutshell

Cosmo is one of the few SIX-listed biopharma companies with sufficient cash resources to fund its clinical development plans and pay dividends thanks to a strong balance sheet and sustainable revenues and profits from 8 marketed products. Its established portfolio, including Lialda/Mezavant and Uceris/Cortiment, both for treating ulcerative colitis, and revenues from drug development and manufacturing for third parties, provides a stable and high-margin revenue stream. Recently launched growth products such as GI Genius, a breakthrough artificial intelligence (AI) enhanced device compatible with all major brands of endoscopes, and Winlevi, the first-ever topical anti-androgen on the US market for treating acne, should provide substantial growth and margin expansion in the near and long-term, with the potential of annual dividends. We qualify Cosmo as a Medium Risk investment due to its stable revenues from a broad range of marketed products.

Life Cycle Positioning - Medium Risk

We qualify Cosmo as Medium Risk due to its solid balance sheet, revenues from eight marketed products (Lialda/Mezavant, Uceris/Cortiment, Aemcolo/Relafalk, Eleview, GI Genius, Byfavo, Winlevi, and Lumeblue), manufacturing revenues for third parties, and financial equity stakes in RedHill (14.8%), PAION (7.3%), and Eagle (0.7%), which can be easily monetized. Cosmo has always been prudent by staying within its financial reach when making investment decisions. Cosmo has returned to sustainable profitability, boosted by the global rollout of its products thanks to commercialization partnerships with strong players such as Medtronic in major markets. (See “Important Research Disclosures” for our Risk Qualification).



SOURCE: VALUATIONLAB

The successful transformation from a manufacturing company to a hybrid pharmaceutical and health-tech company

Cosmo Pharmaceuticals is a hybrid pharmaceutical and health-tech company focused on developing and manufacturing best-in-class treatments in gastroenterology (diseases of the gastrointestinal (GI) tract, dermatology (skin disorders), and health-tech (artificial intelligence (AI) enhanced technology platform), with a staff of 319 employees. The company was founded in 1997 by purchasing the Italian contract manufacturing facility from Parke Davis (when Pfizer acquired Parke Davis) in Lainate (Milan), Italy. Cosmo was gradually transformed into a hybrid gastroenterology and dermatology prescription drug and health-tech development company, generating significant revenues through its commercialization partners. Cosmo was listed on the Swiss Stock Exchange (ticker: COPN) in March 2007. Only a year later, the company became profitable, thanks to the successful launch of its first product Lialda/Mezavant, for treating ulcerative colitis by Shire Pharmaceuticals (acquired by Takeda), reaching peak sales of USD 792 mn before generics entered the market. In December 2021, Cosmo reacquired its dermatology franchise Cassiopea, an earlier spin-off of its dermatology pipeline listed on the SIX Swiss Stock Exchange in 2015. Dermatology products such as Winlevi for acne should also contribute strongly to Cosmo's revenues. Cosmo is a Dutch entity incorporated in the Netherlands, headquartered in Dublin, Ireland, and manufacturing facilities in Lainate, Italy. Since April 2021, Cosmo has traded on XETRA (ticker: C43) in Frankfurt to provide easier access and visibility to European investors and increase overall liquidity in the trading of Cosmo shares.

Cosmo is engaged in the business fields:

- 1) **HEALTH TECH:** AI-enhanced technology platform to improve and support visual diagnosis:
 - **GI Genius** (artificial intelligence-enhanced colonoscopy device): EU launch October 2019, US launch May 2021 by global partner Medtronic)
- 2) **DERMATOLOGY:** treatments for skin disorders include:
 - **Winlevi** (acne vulgaris): launched in the US in November 2021 by Sun Pharma, which has exclusive rights for the US, Japan, Australia, New Zealand, Brazil, Mexico, and Russia; 3SBio for Greater China (China, Taiwan, Hong Kong, and Macau); InfectoPharm for Germany, Italy, and Austria; Hyphens Pharma has for Southeast Asia; and Hyundai Pharmaceuticals for South Korea.
 - **Breezula** (androgenic alopecia): phase III trials started in June 2023, with results due at the end of 2024 or the beginning of 2025; mixed POC results in female hair loss (further clinical development to be determined)
- 3) **GASTROENTEROLOGY:** treatments for digestive system disorders include:
 - **Lialda/Mezavant** (ulcerative colitis): marketed by Takeda/Giuliani/Nogra.
 - **Uceris/Cortiment** (ulcerative colitis): sold by Bausch Health/Ferring.
 - **Aemcolo/Relafalk** (travelers' diarrhea (TD) / irritable bowel syndrome – diarrhea-predominant (IBS-D)): approved for travelers' diarrhea in US and EU in November 2018; Dr. Falk is the development & commercialization partner in EU/ROW; RedHill in the US; positive phase II IBS-D results in January 2021, phase III IBS-D development in planning but needs a new US partner with RedHill not in a financial position to fund the phase III trials together with Dr. Falk.

- **Lumebblue** (lesion detection dye for entire colon): approved in the EU in August 2020, EU rights licensed to Alfasigma SpA in February 2021; Chinese rights licensed to China Medical System (CMS) Holdings in December 2020; in discussions with the FDA if a second confirmatory phase III trial for US approval is needed after CMS reported a positive phase III trial in China; US partnering agreement is required for a US launch.
- **Eleview** (dyed lesion resection cushion): Medtronic is the global commercialization partner, excluding Canada (Pendopharm).
- **Byfavo** (fast-acting sedation for colonoscopy): approved in the US in 2020; Eagle Pharmaceuticals is now responsible for commercialization; Cosmo only benefits from its equity stake in PAION and Eagle and is eligible for up to EUR 105 mn in potential milestone payments.
- **Qolotag** (lesion detection dye for sigmoid colon): approved in the EU.
- **CB-01-33 / colesevelam** (bile acid diarrhea): preclinical development; the formulation and IP protection have been completed, and clinical development is in planning
- **Manufacturing pharmaceutical products for third parties** (at Cosmo's GMP-approved plant) and related services (e.g., product formulations & stability evaluations, document preparation for pharmaceutical product registration).

A business model based on three pillars to increase opportunities and reduce risk

Cosmo aims to achieve superior long-term returns on investment by applying an entrepreneurial approach to assessing opportunities and risks. Existing financial resources need to be available for all projects before the company decides to start clinical development. Its business model is based on three pillars to increase opportunities and decrease risk, including

- 1) **Development and manufacturing of its products**
- 2) **Selective strong partnerships to commercialize these products**
- 3) **Drug development and manufacturing on behalf of third parties**

This enables Cosmo to focus on multiple R&D opportunities, and have a lean and straightforward cost base, not bearing the cost for commercial infrastructure, thereby increasing profitability as new products generate revenues.

Global sales infrastructure established, leading to increasing profitability

Through strategic partnerships, Cosmo has established a global sales infrastructure for almost all its major products except for Lumebblue in the US. Cosmo commercializes its products through selective players in exchange for:

- **Equity, milestones, and royalties:** Aemcolo US (14.8% stake in RedHill)
- **Equity stakes and milestones:** Byfavo US (0.7% stake in Eagle Pharmaceuticals, which acquired Acacia in June 2022) and a 7.3% stake in PAION), with Cosmo eligible for up to EUR 105 mn sales milestones
- **Milestones and royalties:** Lialda (Shire/Takeda/Giuliani); Uceris US (Bausch Health); Cortiment ROW (Ferring); Relafalk ROW (Dr. Falk); Lumebblue EU (Alfasigma), Lumebblue China (China Medical System Holdings); Winlevi US, Japan,
- **Revenue split:** GI Genius, Eleview, and all upcoming medical devices (Medtronic)

The value of Cosmo's equity-for-product stakes in its commercialization partners amounts to EUR 7.5 mn. Cosmo benefits from milestones and royalties of its partnered products and the long-term value creation of its partner's entire product and pipeline portfolio, which should further boost the value of its equity stakes.

Success in the USD 75 bn colonoscopy market should be transformational.

Colorectal cancer is the third most common cancer diagnosed in the US, which can largely be prevented by timely and regular screening through, e.g., colonoscopy. Cosmo's endoscopy product pipeline, with a particular focus on cancer prevention through improved colonoscopies, targets a large market opportunity. With an estimated 19 mn colonoscopies per year in the US with an average cost of USD 3,081 per procedure (according to Blue Cross Blue Shield) and an additional 25 mn in EU/ROW (conservative number) with an assumed cost of USD 655 per procedure (2012 Comparative Price Report), we estimate the global market amounts to almost USD 75 bn per year. Additional costs of polyp removal and biopsy testing (USD ~200-300 per polyp) are excluded from these numbers. This number is set to grow with the aging of the population and structured cancer screening programs. Even low penetration rates for Cosmo's endoscopy products could be transformational, boosted further by capturing more value in the lucrative US market through the GI Genius and Eleview partnership with Medtronic, the world's leading medical device company with considerable marketing muscle.

Targeting a USD 20+ bn IBD market driven by biologics and new treatments

According to Evaluate Pharma, Cosmo's gastrointestinal drugs target a global IBD (inflammatory bowel disease) drug market estimated at USD 19.8 bn in 2020 which is expected to increase to USD 20.3 bn in 2026. Biologic therapies such as Abbvie's JAK1 inhibitor Rinvoq (upadacitinib tartrate) or JNJ's IL-12/23 monoclonal antibody Stelara (ustekinumab) are expected to be the main drivers of growth over the forecast period due to increased use and substantially higher treatment costs than other IBD treatments such as 5-ASA's, corticosteroids, antibiotics, and immunosuppressants. IBD affects approximately 0.5% of the Western global population. The primary forms of IBD are Crohn's disease and ulcerative colitis. The ulcerative colitis market is valued at USD 6.8 bn. The 5-ASA market dropped to around USD ~430 mn in 2020 from a USD 2 bn peak in 2016 due to the lack of new branded treatments and the emergence of generics impacting the lucrative US market. Nevertheless, Cosmo's treatments for ulcerative colitis, Lialda/Mezavant, and Uceris/Cortiment have established substantial market penetration due to their improved efficacy and safety profile.

New antibiotics needed for colon infections due to increasing bacterial resistance

Cosmo's therapeutic focus also includes colon infections caused by bacteria. These infections are among the most encountered in primary care and span a wide range of diseases, which typically cause (bloody) diarrhea, dehydration, and fever. While they may not always be severe and often resolve rapidly, they can be serious in specific healthcare settings or patient populations. Cosmo's novel antibiotic rifamycin SV MMX (branded "Aemcolo" in the US and marketed by RedHill and branded "Relafalk" in Dr. Falk territories outside the US) targets travelers' diarrhea and IBS-D (irritable bowel syndrome – diarrhea-predominant) among others, which affect tens of millions of people annually, with increasing bacterial resistance to current antibiotic treatments.

Proprietary “MMX” technology provides the base for new best-in-class GI drugs

At the core of Cosmo’s product pipeline is the proprietary “MMX” (**M**ulti-**M**atri**X**) technology, a patented oral controlled-release formulation technology for off-patent drugs that target the gastrointestinal tract. The MMX technology provides an excellent base for developing new, patentable products with a lower risk than NCEs (new chemical entities) with a unique once-a-day dosing regimen. Cosmo may also target riskier NCEs with a longer composition of matter patent protection to extend its business model now that the MMX formulation patent expired in 2020.

Artificial intelligence is a new and revolutionary pillar of growth for Cosmo

Artificial intelligence (AI) is an emerging technology that will become a new and revolutionary pillar of growth that should generate substantial revenues for Cosmo, starting in endoscopy with potential additional applications. In our view, GI Genius, combined with the global marketing muscle of Medtronic, is set to become a game-changer in colonoscopy. This real-time automatic polyp detection system based on AI can be seen as a “second set of eyes” that will alert the endoscopist more consistently and reliably than a human assistant (and at significantly lower costs). Additional upgrades such as optical biopsy, other gastrointestinal applications, or procedural documentation and administration could make this an invaluable system in colonoscopy. Other endoscopy products such as Eleview (lesion resection) and Lumebblue (lesion enhancing detection dye) can piggyback on the success of GI Genius and the Medtronic partnership.

Near-term key priorities and strategy in the next 12-18 months:

- **GI Genius:** expand AI-enhanced colonoscopy in the US, across all EU member states, and ROW by global partner Medtronic; host and accelerate an ecosystem of new apps on GI Genius through expanded cooperation with Medtronic.
- **Winlevi:** increase the number of users and revenues in the US by partner Sun Pharma; expand the franchise globally by seeking regulatory approval in key markets outside the US and signing on commercialization partners for these regions, e.g., Sun Pharma territory expansion agreement (Japan, Australia, New Zealand, Brazil, Mexico, Russia), 3SBIO (Greater China), InfectoPharm (Germany, Italy, Austria), Hyphens Pharma (Southeast Asia), Hyundai Pharmaceuticals (South Korea).
- **Lumebblue:** licensed in the EU, Switzerland, EEA countries, Russia, and Mexico by partner Alfasigma; discuss with US FDA the need for a second phase III trial after the positive outcome of the phase III trial in China run by CMS; contract a US commercialization partner, conclude commercialization partnerships for major markets outside the EU (Alfasigma) and China (CSM Holdings).
- **Aemcolo/Relafalk:** successfully relaunch in travelers’ diarrhea by RedHill in the US and by Dr. Falk in the EU; finalize discussions with the US and EU regulators to start phase III trials in IBS-D; seek new US partner to fund IBS-D phase III development, out license ROW rights (ex-US & EU).
- **Eleview:** advance launch in the US/ROW with global partner Medtronic and Canada (Pendopharm).
- **CB-03-10:** advance phase I clinical trial in patients with solid tumors.
- **CB-01-33 / colesevelam:** start phase II POC trial in H2 2023.
- **Expand pipeline:** assess new chemical entities as possible MMX projects or in-license new GI, endoscopy, and dermatology treatments; potentially host an R&D Day to discuss new pipeline projects.

Sustainable cash generation to fund all development plans and pay dividends

Cosmo's gross cash position (including bonds) of EUR 222 mn (CHF 213 mn) on 30 June 2023, together with additional milestone payments and increasing royalty and manufacturing income, is sufficient to finance all development and commercialization plans, paying a dividend and repaying the EUR 175 mn convertible bonds in November 2023. The substantial cash position is targeted to expand Cosmo's product offering through internal development projects and external transactions.

Valuation Overview

Risk-adjusted sum-of-parts NPV points to CHF 92 per share

We derive a risk-adjusted (r)NPV for Cosmo of CHF 92 per share with gross cash and bonds of CHF 13 per share (30 June 2023) and overhead expenses (conservatively including the repayment of the EUR 175 mn convertible bonds in November 2023) of CHF 17 per share with a WACC of 7% (reflecting the low Swiss interest environment).

SUM OF PARTS							
PRODUCT NAME	INDICATION	PEAK SALES (EUR MN)	LAUNCH YEAR (EST)	UNADJUSTED NPV/SHARE	SUCCESS PROBABILITY	RISK-ADJUSTED NPV/SHARE	PERCENTAGE OF TOTAL
HEALTH TECH:							
GI GENIUS	AI ENHANCED COLONOSCOPY	285	2019 (EU) / 2021 (US)	17	100%	17	16%
DERMATOLOGY:							
WINLEVI (TOPICAL ANTI-ANDROGEN)	ACNE	372	2021 (US) / 2025 (EU)	25	82.5%	21	19%
BREEZULA (TOPICAL ANTI-ANDROGEN)	ALOPECIA (HAIR LOSS, MEN)	378	2026	18	65%	12	11%
GASTROENTEROLOGY:							
LIALDA / MEZAVANT	ULCERATIVE COLITIS	709	2007	13	100%	13	12%
UCERIS / CORTIMENT	ULCERATIVE COLITIS	72	2013	3	100%	3	3%
ELEVIEW	LESION RESECTION CUSHION	66	2017	4	100%	4	3%
AEMCOLO / RELAFALK	TRAVELERS' DIARRHEA	30	2019	2	100%	2	2%
AEMCOLO / RELAFALK	IBS-D	373	2026	22	50%	11	10%
LUMEBLUE	LESION DETECTION DYE	92	2020 (EU) / 2026 (US)	5	82.5%	4	4%
BYFAVO (MILESTONES ONLY)	FAST-ACTING SEDATION	162	2020	1	100%	1	1%
CB-01-33 (COLESEVELAM) NEW	BILE ACID DIARRHEA	TBD	TBD	TBD	<15%	TBD	
CONTRACT MANUFACTURING				7		7	6%
CB-03-10	ONCOLOGY (NON-CORE)	TBD	TBD	TBD	<15%	TBD	
EQUITY FOR PRODUCT STAKES E.G. REDHILL (14.8%); PAION (6.8%); EAGLE (0.7%)				0		0	0%
CASH & SHORT-TERM INVESTMENTS (30 JUNE 2023)		222		13		13	12%
TOTAL ASSETS				132		108	100%
OVERHEAD EXPENSES (INCL. REPAYMENT OF EUR 175 MN CONVERTIBLE BOND IN 2023)				-17		-17	
NPV/SHARE (CHF)				116		92	
SHARE PRICE ON 06 AUGUST 2023						45	
PERCENTAGE UPSIDE / (DOWNSIDE)						105%	
* NOTE: 16.3 MN SHARES USED FOR NPV/SHARE CALCULATION AS WE ASSUME PAY BACK EUR 175 MN CONVERTIBLE BOND IN 2023 (INCLUDED IN OVERHEAD EXPENSES) NOTE: 17.5 MN SHARES OUTSTANDING INCLUDES 1.2 MN TREASURY SHARES RESERVED FOR POTENTIAL CONVERSION OF THE CONVERTIBLE BOND ESTIMATES AS OF 7 AUGUST 2023							

SOURCE: VALUATIONLAB ESTIMATES

Key drivers of growth for Cosmo include:

1) GROWTH PRODUCTS:

GI Genius (AI-enhanced colonoscopy) – rNPV of CHF 17 per share

GI Genius is the first-ever AI (artificial intelligence)-enhanced device approved for colonoscopy with an estimated 2-3 years lead over competitor devices. Combined with the global marketing muscle of Medtronic, we believe this system will be a game-changer in colonoscopy with substantial upside from future upgrades and additional indications (not in our forecasts). We conservatively forecast peak sales of approximately EUR 300 mn (booked by Medtronic), with Cosmo retaining a net margin above 20%. We calculate an NPV of CHF 17 per share with the device approved and launched in the major global regions. Substantial growth should come from new apps and applications.

Winlevi (acne) - rNPV of CHF 21 per share

Winlevi became the first-ever topical anti-androgen on the US market for treating acne, with good efficacy and an excellent safety and tolerability profile. Winlevi is off to a flying start in the US, triggering an expansion of the Sun Pharma agreement to include Canada, Japan, Australia, New Zealand, Brazil, Mexico, and Russia. Moreover, 3SBIO acquired the exclusive licensing rights of Winlevi for Greater China, followed by InfectoPharm (Germany, Italy, Austria), Hyphens Pharma (Southeast Asia), and Hyundai Pharma (South Korea). We calculate an rNPV of CHF 19/share for Winlevi in acne with an 82.5% success probability, an average of 100% (launched) in the US, and 65% (phase III) in the EU, with global peak

sales, conservatively amounting to around EUR 400 mn.

2) ESTABLISHED PORTFOLIO:

Lialda/Mezavant (ulcerative colitis) - NPV of CHF 13 per share

Lialda/Mezavant (mesalamine MMX) is Cosmo's first prescription drug using its proprietary MMX technology for treating ulcerative colitis and was launched by Shire (acquired by Takeda in 2019) in 2007. Sales peaked at EUR 709 mn in 2016 before cheap generics impacted sales. Cosmo receives manufacturing revenue to produce Lialda tablets for Takeda and its partners. We base our Lialda revenues on the number of tablets shipped, expecting single-digit increases in the next few years. We calculate an NPV of CHF 13 per share.

Uceris/Cortiment (ulcerative colitis) - NPV of CHF 3 per share

Uceris/Cortiment (budesonide MMX) is Cosmo's second treatment for ulcerative colitis with far better economics than Lialda. Ferring commercializes the drug in the EU and ROW (excluding Japan) branded Cortiment, while Bausch Health sells the drug, branded Uceris, in the US. Although the peak sales potential was similar to Lialda, sales likely peaked at EUR 139 mn in 2016 due to the "at-risk" launch of a generic version of Uceris by Actavis (Teva) in the US in 2018. We lowered our US sales to reflect the impact of cheap generics in the US while maintaining a solid uptake outside the US by Ferring. We calculate an NPV of CHF 3 per share.

Eleview (dyed lesion resection cushion) – NPV of CHF 4 per share

Eleview is an injectable lesion resection cushion that allows physicians a faster and less risky excision (removal) of adenoma or polyps discovered during endoscopy. Eleview is injected between the mucosal layers, where it separates and flags them with methylene blue dye for easy removal. Medtronic is responsible for global commercialization except in Canada (Pendopharm), replacing previous agreements with EA Pharma, Olympus, and Fujifilm. We forecast a significant increase in sales after the recall of the competing product Orise (Boston Scientific) with EUR 60+ mn peak sales with an NPV of CHF 4/share.

Aemcolo/Relafalk (TD & IBS-D) – rNPV of CHF 13/share

Aemcolo/Relafalk (rifamycin SV MMX) has potential in TD (travelers' diarrhea) and IBS-D (irritable bowel syndrome – diarrhea predominant), among others. The antibiotic was approved in the US and EU for travelers' diarrhea in November 2018, with its first launch in 2019. Dr. Falk has global rights, excluding the US, where RedHill acquired the rights and sells the drug. Dr. Falk brands the drug Relafalk. Outside Dr. Falk's territories, the antibiotic is branded Aemcolo. Revenues were severely impacted by the global COVID-19 pandemic and restricted travel. We conservatively forecast global peak sales of EUR 30 mn in travelers' diarrhea due to the short treatment duration (3 days) with an NPV of CHF 2 per share. Aemcolo/Relafalk could also be developed in IBS-D, a far larger indication with longer treatment times (~14 days), with global peak sales of EUR 350+ mn and an rNPV of CHF 11 per share with a 50% (phase II completed) success probability. However, a new US partner must be found for the US as RedHill is not in the financial situation to fund phase III development in IBS-D.

Lumebly (colonic lesion detection dye) - rNPV of CHF 4/share

Lumebly is a novel MMX formulation of the existing liquid colon staining dye methylene blue in a more convenient oral tablet with proven clinical efficacy in detecting lesions.

Please see important research disclosures at the end of this document

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Lumebblue was approved in the EU in August 2020 and is complementary to Cosmo's GI Genius as the dye enhances difficult-to-spot lesions even further with higher contrast. The EU rights were out-licensed to Alfasigma, with the first EU launch in Italy in 2022. China Medical System (CMS) Holding acquired the rights for China. Cosmo is in discussions with the FDA if another confirmatory phase III trial is needed for US approval. The positive phase III trial conducted by CMS in China with 1,800 patients could now be considered the second confirmatory phase III trial. We conservatively assume the FDA will require an additional phase III trial with US approval expected in 2025 and the launch by a commercialization partner in 2026. Based on lowered pricing assumptions, we conservatively forecast global peak sales of approximately EUR 90 mn, as total pricing for a colonoscopy may be affected by the additional fees for GI Genius. We calculate an rNPV of CHF 4 per share with a 75% success rate, the average of EU (100%) approved and US (65%) single phase III.

Byfavo (fast-acting sedation) – rNPV of CHF 1 per share

Byfavo (remimazolam) is a fast-acting sedative for procedural sedation in endoscopy and complements Cosmo's endoscopy offering. In 2016, Cosmo acquired US rights from originator PAION and currently holds a 7.3% stake. As of June 2022, Eagle Pharmaceuticals is responsible for commercialization in the US, with Cosmo retaining a 0.7% stake in Eagle. Cosmo will benefit from the long-term value creation through its equity stakes in PAION and Eagle and is eligible to receive a total of up to USD 105 mn payable on Byfavo reaching certain sales milestones. We calculate an NPV of CHF 1 per share for the remaining milestone payments.

Contract Manufacturing 3rd parties – NPV of CHF 7 per share

Cosmo continues to manufacture APIs (active pharmaceutical ingredients) for third parties, including generics and specialty drugs, in the range of approximately EUR 15-20 mn, which adds up to an NPV of CHF 7 per share.

3) PIPELINE PRODUCTS:

Breezula (hair loss) - rNPV of CHF 12 per share

Breezula is a different formulation and 7.5x higher dosage strength of clascoterone than Winlevi for treating androgenic alopecia (AGA), the most common type of hair loss. Positive phase IIb dose-ranging results were reported for Breezula in male alopecia. Phase III development has started in June, with two phase III trials of approximately 750 male subjects aged at least 18 years in around 60 study centers. Topline results are expected at the end of 2024 or the beginning of 2025. We assume the first launches for Breezula to occur in 2026 with peak sales of around EUR 400 mn. We calculate an rNPV of CHF 12/share with a 65% (phase III) success probability for Breezula in male alopecia alone. Currently, we do not include forecasts for female alopecia, although Breezula may be developed for a subgroup of women (under 30 years) based on POC results reported in September 2021.

No value contributed to several pipeline projects, yet

We do not include any forecasts for **CB-03-10** in cancer as the compound currently lacks clinical proof-of-concept (POC), providing a real potential option. CB-03-10 is a synthetic steroidal antiandrogen and is derived from cortexolone, just like the company's dermatology compounds Winlevi (acne) and Breezula (hair loss). In May 2022, Cosmo started a phase I trial of CB-03-10 in up to 90 patients with solid tumors, including pancreas, colon, and prostate cancer, with topline results due in ~18 months from the trial start. On positive phase I results, Cosmo plans to seek a strong oncology partner to fully develop and commercialize

CB-03-10 in return for upfront, development, regulatory and sales milestones, and royalties on sales.

CB-01-33 (colesevelam) is a novel bile acid sequestrant formulation for bile acid diarrhea (BAD) that affects approximately 1% of the population, with the potential to overcome the current concerns for bile acid sequestrant treatments for BAD. A phase II proof-of-concept (POC) for CB-01-33 in bile acid diarrhea is scheduled to start in H2 2023.

“Equity-for-product” investments – NPV of CHF 0 per share

These investments consist of a 14.8% stake in RedHill, a 7.3% stake in PAION, and a 0.7% stake in Eagle, and stakes in VolitionRx (3.5%) and AIMM Therapeutics (6.5%), which adds up to EUR 7.5 mn or CHF 0 per share. Note that Cosmo will benefit not only from the successful launch of its own products by its commercialization partners but also through the value creation of its partners’ product pipeline through its “equity-for-product” stakes.

Sensitivities that can influence our valuation

Development and regulatory risk: We believe the risk is not considerable considering almost all of Cosmo's major products (Lialda/Mezavant, Uceris/Cortiment, Eleview, GI Genius, Aemcolo/Relafalk, Byfavo, Lumeblue, Winlevi) are on the market. Lumeblue has been approved in the EU, and CMS has just concluded a second positive phase III trial in China with 1,800 patients. We assume an 82.5% success rate for Lumeblue, the average of EU (100%) approved and US (65%) phase III development. We assume a 65% success rate for Breezula (male hair loss), which started phase III in June 2023, and a 50% success rate for Aemcolo/Relafalk (IBS-D). A new US partner is needed to fund IBS-D phase III trials.

Pricing and reimbursement: Pricing for products such as Aemcolo and Byfavo is straightforward as there have been comparable branded products on the market treating the same indications to make a good pricing reference. Cosmo has put considerable effort into determining the right market price for its novel colonoscopy products, such as Eleview, GI Genius (determined by Medtronic globally), and Lumeblue (determined by Alfasigma in the EU), which provide cost-effective solutions compared to current standards. In the EU, pricing and reimbursement occur on a country-by-country base, which can lead to differences in the timing of market launch and sales uptake for each member state.

Partnering and commercialization: Product sales will now be entirely dependent on external commercialization partners such as Medtronic (GI Genius/Eleview), RedHill (Aemcolo), Dr. Falk (Relafalk), Acacia (Byfavo), Alfasigma (Lumeblue) and Sun Pharma (Winlevi) to position successfully and market Cosmo's drugs. Cosmo intends to sign a US commercialization partner for Lumeblue before starting the US phase III trial. Global partner Medtronic will be instrumental in the commercial success of GI Genius and Eleview and future medical devices. Actual sales uptake, upfront, regulatory and sales milestones, and sales royalties may differ from our forecasts as the pace of launching and signing on partners, and terms may differ.

Patent and market exclusivity: Cosmo built a comprehensive patent estate protecting its MMX technology and products from generic competition. Several market exclusivities, such as 10 years of data exclusivity in the EU and 5 years of NCE (new chemical entity) exclusivity or QIDP (qualified infectious disease product) designation with 5 years of additional exclusivity, can further extend market protection. Although Lialda enjoyed composition of matter protection until June 2020 in the US (US6773720) and EU (EU1198226, EU1287822), the FDA has approved a generic version of Lialda from the Indian generic manufacturer Zydus. Uceris has US patent protection until September 2031 through various patents. In July 2018, Actavis' generic received FDA approval and has been launched "at-risk". We assume patent protection and/or market exclusivity for Lumeblue (until 2033), Eleview (until 2034), Byfavo (until 2033), Aemcolo/Relafalk (until 2028), Qolotag (until 2035) and GI Genius (until 2039 largely based on trade secrets). Medical use patents protect Winlevi and Breezula until 2022 (EU/ROW) and 2023 (US), while patents covering all crystalline forms provide protection until 2028 (EU/ROW) and 2030 (US). The use patent for CB-06-01 expires in 2023 (EU/ROW) and 2026 (US), while a US provisional application covering the topical composition in acne filed in 2015 extends protection potentially up to 2035. The use patent for CB-06-02 expires in 2025 (EU/ROW) and 2031 (US), while a US provisional application covering the topical composition filed in 2015 extends protection potentially up to 2035.

Catalysts

CATALYST TIMELINES					
TIME LINE	PRODUCT	INDICATION	MILESTONE	COMMENT	IMPACT ON RNPV (CHF/SHARE)
2023					
DURING 2023	WINLEVI	ACNE	LICENSING AGREEMENTS	EXPAND WINLEVI FRANCHISE IN THE REST OF THE WORLD THROUGH LICENSING AND SUPPLY AGREEMENTS WITH DERMATOLOGY COMPANIES	
16 FEB			PRELIMINARY 2022 RESULTS	RECORD TOTAL REVENUE AND OPERATING PROFIT EXCEEDS GUIDANCE; FY 2022 TOTAL REVENUE OF CHF 102.1 MN (2022 GUIDANCE: CHF 90 - 100 MN) AND OPERATING PROFIT OF CHF 28 MN (2022 GUIDANCE: CHF 20 - 25 MN) BOOSTED BY GROWTH PRODUCTS WINLEVI AND GI GENIUS AND LEGACY PRODUCTS LIALDA AND UCERIS/CORTIMENT; FY 2023 GUIDANCE: TOTAL REVENUE OF CHF 110 - 120 MN AND OPERATING PROFIT OF CHF 25 - 35 MN; PHASE III BREEZULA TRIAL IN MALE HAIR LOSS TO START IN Q1 2023	
23 MAR			FY 2022 RESULTS	RECORD FY 2022 RESULTS EXCEED GUIDANCE; SUSTAINABLE CASH AND CASH EQUIVALENTS EUR 187 MN (31 DECEMBER 2022); 2023 GUIDANCE: TOTAL REVENUE: EUR 110 MN (+8%) TO EUR 120 MN (+18%), TOTAL REVENUE (EXCL. MILESTONES): EUR 110 MN (+41%) TO EUR 120 MN (+54%), OPERATING RESULT: EUR 25 MN (-11%) TO EUR 35 MN (+25%); DIVIDEND: EUR 1.05 PER SHARE (+11%)	
30 MAR	LUMEBLUE	LESION DETECTION (ENTIRE COLON)	EXPANSION AGREEMENT WITH CMS	LICENSE AGREEMENT WITH CHINA MEDICAL SYSTEMS HOLDINGS (CMS) EXPANDED BEYOND EXISTING TERRITORIES (GREATER CHINA INCLUDING CHINA, HONG KONG, MACAO, TAIWAN) TO INCLUDE SEVERAL COUNTRIES BELONGING TO THE "PAN-ASIA" REGION INCLUDING COUNTRIES IN CENTRAL ASIA, EASTERN ASIA, SOUTHEASTERN ASIA AND SOUTHERN ASIA. NO TERMS WERE DISCLOSED.	
26 MAY			AGM	SHAREHOLDERS APPROVE ALL AGENDA ITEMS AT ANNUAL GENERAL MEETING (AGM)	
20 JUN	WINLEVI	ACNE	APPROVAL CANADA	PARTNER SUN PHARMA RECEIVED MARKETING AUTHORIZATION FOR WINLEVI TO TREAT ACNE IN CANADA	
22 JUN	WINLEVI	ACNE	LICENSING AGREEMENT HYUNDAI PHARMA FOR SOUTH KOREA	HYUNDAI PHARMACEUTICAL SIGNED AN EXCLUSIVE LICENSING AGREEMENT FOR WINLEVI IN SOUTH KOREA WITH COSMO TO RECEIVE AN UNDISCLOSED UPFRONT PAYMENT, POTENTIAL REGULATORY AND SALES MILESTONES AND CUSTOMARY DOUBLE-DIGIT ROYALTIES ON NET SALES. COSMO WILL BE THE EXCLUSIVE SUPPLIER OF WINLEVI.	
28 JUN	CORTIMENT	ULCERATIVE COLITIS	JAPAN APPROVAL	PARTNER FERRING PHARMACEUTICALS RECEIVED APPROVAL IN JAPAN, THE SECOND LARGEST INFLAMMATORY BOWEL DISEASE (IBD) MARKET; FIRST SALES IN JAPAN ARE EXPECTED TO BEGIN BY END Q3 2023	
29 JUN	BREEZULA	MALE ALOPECIA	START PHASE III TRIALS "SCALP 1" & "SCALP 2"	START PHASE III DEVELOPMENT OF BREEZULA IN MALE ALOPECIA CONSISTING OF TWO IDENTICAL 6-MONTH RANDOMIZED, DOUBLE-BLIND PHASE III TRIALS DUBBED "SCALP 1" (~750 SUBJECTS IN THE US & GEORGIA) AND "SCALP 2" (~750 SUBJECTS IN THE US, GERMANY, POLAND), EACH FOLLOWED BY A 6-MONTH SINGLE-BLIND TREATMENT WITH WINLEVI, CONDUCTED IN ABOUT 60 CENTERS AND A TOTAL OF 1,500 MALE SUBJECTS AGED OVER 18; CO-PRIMARY ENDPOINTS ARE TARGET AREA HAIR COUNT (TAHC) AND PATIENT REPORTED OUTCOME (PRO); TOPLINE RESULTS EXPECTED END 2024/EARLY 2025	
26 JUL			H1 2023 RESULTS	STRONG H1 2023 RESULTS WITH REVENUE +5.3% TO EUR 43.7 MN (BOOSTED BY GI GENIUS, LIALDA, ELEVIEW & CONTRACT MANUFACTURING; NOTE: H1 2022 REVENUE BOOSTED BY CHF 8 MN CORTIMENT SALES MILESTONE); NET EXPENSES UP +9.3% TO EUR 36.5 MN DUE TO INCREASED GI GENIUS FINISHED GOODS SOLD; OPERATING PROFIT DECLINED -12% TO EUR 7.1 MN; PROFIT BEFORE TAX OF EUR 3.7 MN (H1 2022: EUR 9.1 MN); FULL YEAR 2023 GUIDANCE REAFFIRMED: TOTAL REVENUES: EUR 110-120 MN (+8% TO +18%); OPERATING PROFIT: EUR 25-35 MN (-11% TO +25%)	
H2	WINLEVI	ACNE	EU FILING	FILING IN THE IMPORTANT EU MARKET	+ CHF 2
H2	CB-01-33 (COLESEVELAM)	BILE ACID DIARRHEA	START PHASE II POC TRIAL	FORMULATION AND IP PROTECTION COMPLETED, DRAFTING CLINICAL PROTOCOL TO START PHASE II POC TRIAL IN H2 2023	
TBD	AEMCOLO / RELAFALK	IBS-D	START PHASE III	SEEKING NEW PARTNER BEFORE STARTING PHASE III DEVELOPMENT (TRIAL DURATION OF ~18 MONTHS) OF SECOND INDICATION IN IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D)	+ CHF 3
TBD	LUMEBLUE	LESION DETECTION (ENTIRE COLON)	US PARTNERING FIRST / US PHASE III NEEDED?	DISCUSS WITH FDA IF POSITIVE PHASE III TRIAL IN CHINA COULD BE SUFFICIENT FOR US APPROVAL; OTHERWISE FINALIZE PROTOCOL AND STATISTICAL ANALYSIS PLAN FOR 2ND CONFIRMATORY PHASE III TRIAL REQUIRED FOR US APPROVAL; START OF TRIAL ONLY AFTER CONCLUDING A US (CO-)DEVELOPMENT AND COMMERCIALIZATION AGREEMENT	+ CHF 0.3
AROUND YEAR-END	GI GENIUS	AI-ENHANCED LESION DETECTION PLATFORM	NEW APPS	EXPAND GI GENIUS BUSINESS WITH METTRONIC THROUGH NEW APPS INCLUDING THIRD-PARTY DEVELOPERS WITH THE PLATFORM NOW OPEN TO NEW DEVELOPERS	

ESTIMATES AS OF 7 AUGUST 2023

SOURCE: VALUATIONLAB, COSMO PHARMACEUTICALS

Income Statement

COSMO PHARMACEUTICALS											SHARE PRICE (CHF)	44.70
IFRS												
INCOME STATEMENT (EUR MN)	2022	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	
PRODUCT SALES (INCL. PARTNER SALES)	472	496	666	815	1,344	1,895	1,979	1,928	1,612	1,272	1,090	
CHANGE (%)	36%	5%	34%	22%	65%	41%	4%	-3%	-16%	-21%	-14%	
TOTAL MANUFACTURING:	66	64	86	137	161	186	192	167	137	97	86	
CHANGE (%)	52%	-3%	29%	60%	88%	15%	19%	-13%	-18%	-29%	-12%	
1) MANUFACTURING OF OWN PRODUCTS	53	50	72	123	147	171	177	152	121	81	69	
CHANGE (%)	62%	-6%	35%	72%	105%	17%	21%	-14%	-20%	-33%	-14%	
2) MANUFACTURING GENERICS, SPECIALTY DRUGS & RELATED SERVICES	13	14	14	14	15	15	15	15	16	16	16	
CHANGE (%)	4%	5%	2%	2%	2%	2%	2%	2%	2%	2%	2%	
LICENCE AND UPFRONT FEES AND MILESTONES	24	34	42	144	55	86	52	76	27	15	20	
ROYALTIES TO COSMO	10	15	43	69	180	283	304	290	229	167	133	
CHANGE (%)	15%	48%	336%	59%	317%	58%	69%	-4%	-21%	-27%	-20%	
OTHER REVENUES FROM SALES	2	1	1	1	1	1	1	1	1	1	1	
CHANGE (%)	19%	-16%	-16%	0%	0%	0%	0%	0%	0%	0%	0%	
TOTAL REVENUES (COSMO)	102	114	172	352	397	557	549	535	394	279	240	
CHANGE (%)	57%	12%	51%	104%	13%	40%	-1%	-3%	-26%	-29%	-14%	
COGS	-40	-42	-51	-74	-124	-154	-165	-157	-119	-79	-58	
CHANGE (%)	47%	4%	25%	46%	144%	24%	33%	-5%	-24%	-33%	-27%	
GROSS PROFIT	62	72	122	277	273	403	384	378	275	200	182	
CHANGE (%)	92%	16%	70%	128%	-2%	48%	-5%	-2%	-27%	-27%	-9%	
MARGIN (%)	60%	63%	71%	79%	69%	72%	70%	71%	70%	72%	76%	
R&D	-16	-22	-20	-11	-11	-12	-12	-13	-13	-14	-14	
CHANGE (%)	37%	42%	-10%	-44%	0%	5%	5%	5%	5%	5%	-2%	
S,G&A	-20	-20	-20	-21	-21	-21	-21	-21	-21	-21	-21	
CHANGE (%)	90%	2%	1%	1%	1%	1%	1%	1%	1%	1%	1%	
AS % OF REVENUES	19.5%	17.9%	11.9%	5.8%	5.2%	3.7%	3.8%	3.9%	5.4%	7.6%	8.9%	
OTHER OPERATING INCOME / (EXPENSES)	2	1	1	1	1	1	1	1	1	1	1	
NET OPERATING EXPENSES	-34	-41	-39	-31	-31	-31	-32	-33	-34	-34	-34	
CHANGE (%)	60%	24%	-5%	-22%	0%	2%	2%	2%	2%	2%	-1%	
EBIT	28	30	82	247	242	372	352	345	242	166	148	
CHANGE (%)	153%	8%	172%	200%	-2%	54%	-5%	-2%	-30%	-31%	-11%	
MARGIN (%)	27.5%	26.5%	47.7%	70.1%	60.9%	66.7%	64.2%	64.5%	61.3%	59.3%	61.7%	
EBITDA	35	38	91	256	252	382	364	357	255	180	164	
CHANGE (%)	92%	8%	138%	182%	-2%	52%	-5%	-2%	-29%	-29%	-9%	
MARGIN (%)	35%	33%	53%	73%	63%	69%	66%	67%	65%	65%	68%	
NET FINANCIAL INCOME / (EXPENSES)	-4	-5	7	9	12	17	20	26	31	39	50	
PROFIT BEFORE TAXES	24	25	89	256	254	389	372	371	272	205	198	
CHANGE (%)	2%	3%	254%	188%	-1%	53%	-4%	0%	-27%	-25%	-4%	
TAXES	-7	-8	-19	-48	-55	-86	-84	-86	-62	-43	-35	
TAX RATE (%)	28.5%	33.2%	20.8%	18.7%	21.8%	22.1%	22.5%	23.2%	22.6%	20.8%	17.9%	
NET PROFIT/(LOSS)	18	17	70	208	199	303	289	285	211	162	162	
CHANGE (%)	-19%	-4%	319%	195%	-5%	53%	-5%	-1%	-26%	-23%	0%	
MARGIN (%)	17.1%	14.7%	40.9%	59.2%	50.1%	54.4%	52.6%	53.3%	53.5%	58.1%	67.7%	
PROFIT/(LOSS) PER SHARE (IN EUR)	1.05	0.96	4.02	11.87	11.32	17.28	16.45	16.26	12.02	9.26	9.24	
PROFIT/(LOSS) PER SHARE (IN CHF)	1.04	0.93	3.89	11.51	10.98	16.75	15.94	15.76	11.65	8.97	8.96	

ESTIMATES AS OF 7 AUGUST 2023

SOURCE: VALUATIONLAB ESTIMATES

FY 2023 guidance:

- **Total revenue:** EUR 110 mn (+7.7%) to EUR 120 mn (+17.5%)
- **Operating profit:** EUR 25 mn (-10.7%) to EUR 35 mn (+25%)

Ratios & Balance Sheet

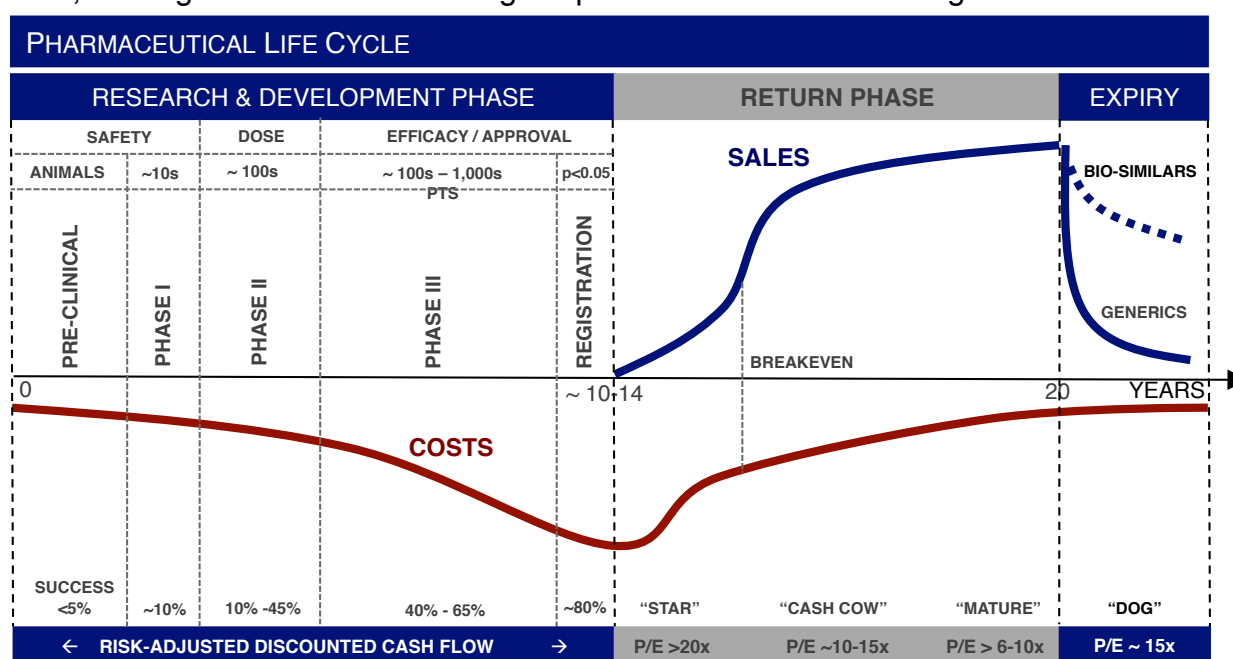
COSMO PHARMACEUTICALS											SHARE PRICE (CHF)	44.70
IFRS												
RATIOS	2022	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	
P/E	48.2x	11.5x	3.9x	4.1x	2.7x	2.8x	2.8x	3.8x	5.0x	5.0x		
P/S	7.1x	4.7x	2.3x	2.0x	1.5x	1.5x	1.5x	2.1x	2.9x	3.4x		
P/NAV	1.7x	1.5x	1.1x	0.8x	0.6x	0.5x	0.4x	0.4x	0.4x	0.3x		
EV/EBITDA	15.0x	6.3x	2.2x	2.3x	1.5x	1.6x	1.6x	2.2x	3.2x	3.5x		
PER SHARE DATA (CHF)												
EARNINGS	1.04	0.93	3.89	11.51	10.98	16.75	15.94	15.76	11.65	8.97	8.96	
CHANGE (%)	-25%	-11%	319%	195%	-5%	53%	-5%	-1%	-26%	-23%	0%	
CASH	14.61	5.47	10.87	25.53	40.12	62.22	83.44	104.65	120.46	132.60	144.40	
CHANGE (%)	2%	-63%	99%	135%	57%	55%	34%	25%	15%	10%	9%	
DIVIDENDS	0.95	1.05	1.17	1.29	1.44	1.59	1.77	1.96	2.18	2.42	2.69	
YIELD (%)	2%	2%	3%	3%	3%	4%	4%	4%	5%	5%	6%	
NET ASSET VALUE	28.11	26.55	30.45	41.95	52.93	69.68	85.62	101.38	113.03	122.00	130.96	
CHANGE (%)	-15%	-6%	15%	38%	26%	32%	23%	18%	11%	8%	7%	
BALANCE SHEET (EUR MN)												
NET LIQUID FUNDS	241	99	197	462	726	1,126	1,510	1,894	2,180	2,400	2,613	
TOTAL ASSETS	760	618	715	981	1,245	1,645	2,029	2,413	2,699	2,918	3,132	
TOTAL SHAREHOLDERS' EQUITY	464	481	551	759	958	1,261	1,550	1,835	2,046	2,208	2,370	
- CHANGE IN %	-10%	4%	15%	38%	26%	32%	23%	18%	11%	8%	7%	
- RETURN ON EQUITY	4%	3%	13%	27%	21%	24%	19%	16%	10%	7%	7%	
TOTAL EQUITY	464	481	551	759	958	1,261	1,550	1,835	2,046	2,208	2,370	
FINANCIAL DEBT	174	156	141	127	114	103	92	83	75	67	61	
EMPLOYEES	295	319	322	325	329	332	335	339	342	345	349	
- CHANGE IN %	7%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	
CASH FLOW STATEMENT (EUR MN)												
PROFIT / (LOSS) BEFORE TAXES	24	25	89	256	254	389	372	371	272	205	198	
DEPRECIATION & AMORTIZATION	7	8	9	9	10	11	12	13	14	15	16	
OTHER NON-CASH ITEMS	1	0	0	0	0	0	0	0	0	0	0	
CASH FLOWS FROM OPERATING ACTIVITIES	33	33	98	265	264	400	384	384	286	220	214	
CASH FLOWS FROM INVESTING ACTIVITIES	2	0	0	0	0	0	0	0	0	0	0	
FREE CASH FLOW	35	33	98	265	264	400	384	384	286	220	214	
CASH FLOWS FROM FINANCING ACTIVITIES	-46	-175	0	0	0	0	0	0	0	0	0	
NET FOREIGN EXCHANGE DIFFERENCES	-2											
CHANGE IN LIQUID FUNDS	-11	-142	98	265	264	400	384	384	286	220	214	
ESTIMATES AS OF 7 AUGUST 2023												
SOURCE: VALUATIONLAB ESTIMATES												

Cash and cash equivalents of EUR 222 mn (30 June 2023) and sustainable cash flows are sufficient to fund all development programs and to pay back the EUR 175 mn convertible bonds on 28 November 2023.

APPENDIX

Pharmaceutical life cycle

To determine the value of a prescription (bio)pharmaceutical compound, it is critical to understand its life cycle. Fortunately, all compounds follow the same life cycle. The clock starts ticking after the compound is patented, providing 20 years of protection from generic competition. Market exclusivities can extend this protection period. The average Research & Development Phase takes 10-14 years, leading to an effective Return Phase of 6-10 years. The Development Phase has 3 distinct Phases, focused on safety (Phase I), dose (Phase II), and efficacy/clinical benefit (Phase III). The compound is filed for registration/approval at the FDA (US) or EMA (EU). The Return Phase is characterized by a star, cash cow, and mature phase. After patent expiry (or loss of market exclusivity) generic manufacturers may copycat the branded prescription drug, at significantly lower costs, leading to a sales and earnings implosion of the branded drug.



SOURCE: VALUATIONLAB

Success probabilities & royalties

Our risk-adjusted NPV calculations use standardized success probabilities based on historical clinical success rates—the success rate increases as the project progress through development. Sales and earnings forecasts are based on the clinical and competitive profile of the compound. The more advanced the compound is, the more accurate the forecasts become as the target market can be defined. We conservatively exclude projects that lack Phase IIa proof-of-concept data in our valuations.

SUCCESS PROBABILITIES & ROYALTIES

DEVELOPMENT STAGE	AIM	WHAT / WHO	SUCCESS PROBABILITY (%)	COSTS (USD MN)	ROYALTIES (%)
PRE-CLINICAL	SAFETY & PHARMACOLOGY DATA	LAB TESTS / ANIMALS - NO HUMANS!	< 5	3	
PHASE I	SCREENING FOR SAFETY	HEALTHY VOLUNTEERS (10'S)	5-15	3	< 5
PHASE II A	PROOF-OF-CONCEPT	PATIENTS WITH DISEASE (10'S)	10-20		
PHASE II	ESTABLISH THE TESTING PROTOCOL	PATIENTS WITH DISEASE (100'S)	15-35	5	5-15
PHASE II B	OPTIMAL DOSAGE	PATIENTS WITH DISEASE (100'S)	20-45	5-10	
PHASE III	EVALUATE OVERALL BENEFIT/RISK	PATIENTS WITH DISEASE (1,000'S)	40-65	> 20-1,000	10-25
REGULATORY FILING	DETERMINE PHYSICIAN LABELING	CLINICAL BENEFIT ASSESSMENT	80-90		
APPROVAL	MARKETING AUTHORIZATION	PHYSICIANS FREE TO PRESCRIBE	100		15-30

SOURCE: VALUATIONLAB, TUFTS, FDA, EMA, CLINICALTRIALS.GOV

Important Research Disclosures

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Our financial analyses are based on the "Directives on the Independence of Financial Research" issued by the Swiss Bankers Association in January 2008.

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Risk Analysis

Speculative	less than 1 year cash and breakeven beyond 1 year
High Risk	profitable within 2 years and 1 approved product/key indication (patent expiry > 5 years)
Medium Risk	profitable and/or sales from at least 2 marketed products/key indications (patent expiry > 5 years)
Low Risk	profitable and sales from >2 marketed products/key indications (patent expiry > 5 years)

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