OCTAVIAN

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INITIATION

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SANTHERA

HOLD – PT CHF 12

Setting a New Standard of Care

We are initiating coverage on Santhera Pharmaceuticals with a HOLD rating and a price target of CHF 12 (+15% upside). Santhera's lead asset Agamree (vamorolone) was recently FDA-approved for the rare disease Duchenne Muscular Dystrophy (DMD), and EMA approval is imminent. Agamree is a novel steroid-like drug that was shown in clinical studies to offer a more benign side effect profile compared to the current standard of care glucocorticoid. As such, we see the potential for Agamree to replace a significant share of currently used steroids, alone or in combination with other approaches such as gene therapy. The commercial launch of Agamree will start in Q1-24E. In North America, Agamree is partnered with and will be commercialized by US-based Catalyst Pharmaceuticals. In key EU markets, Santhera will go directly with a small direct sales force. We estimate peak sales of CHF 132m in Western EU territories for Agamree, and CHF 278m in the US, where Santhera will receive royalties on sales. Including ROW, we see a global peak sales potential of CHF 450m (2031E). We estimate that Santhera has a cash runway into early Q1-25E and that additional cash injections of CHF 50m are required to be funded through to profitability, expected by 2026E. While we are positive on the overall investment case and the differentiated profile of Agamree, we initiate coverage with a HOLD given the currently limited visibility on final product pricing, coupled with possible concerns over funding, that could limit the stock's appreciation potential in the near term.

Bloomberg	SANN SW
Market Cap.	CHF 110m
Price (11.12.23)	CHF 10.40
Price Target	CHF 12
Rating	HOLD

Upcoming Milestones for Vamorolone

EMA approval: Dec 18, 2023E
UK approval: Dec-23E
Commercial launch US: Q1-24E
Commercial launch EU: Q1-24E (Germany), Q2-24E (UK)
Early access program (F): H1-24E
Update new indications: H1-24E
Initial data from Phase IV: Q4-24E
Source: Octavian

- **Peak sales of CHF 450m in DMD:** Following US regulatory approval of vamorolone in DMD, the investment case is significantly de-risked. With a better tolerability profile but comparable efficacy, we see the potential to switch up to 45-50% of steroid users to Agamree. The indication range for vamorolone, as an alternative to corticosteroids, could be expanded to additional areas beyond DMD (focus on rare diseases); an update on potential development strategies is expected during 2024E.
- **Our PT of CHF 12** is based on our rNPV model (15.0% WACC). We only include revenues from Agamree in the indication DMD. Further, we reflect the full dilution from the assumed equity/funding measures in our model (OctE: in total CHF 50m in 2024/25E).
- **Potential risks** to our forecasts include (1) reimbursement/pricing (for EU likely known by mid-24E; US in Q1-24E), and (2) the potential impact of gene therapy on long-term steroid use. In addition, we note risks related to securing funding.
- **Key milestones** will be EMA approval (expected on December 18, 2023) and commercial launch in the US (Q1-24E) and in Germany (Q1-24E). Additional data to strengthen the differentiated safety profile is anticipated to be available by end-24E.

SAMPLE

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DISCLOSURES AND ANALYST CERTIFICATIONS ARE LOCATED IN APPENDIX 1

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Investment Case Summary

Investment Triggers

- Santhera is close to the commercial launch of its **lead asset Agamree (vamorolone), a new therapeutic option for DMD**. DMD is a debilitating rare disease, affecting ~30-35'000 boys and young men in US/EU combined. As a "dissociative steroid" with a **better tolerability profile, at comparable efficacy**, Agamree has the potential to replace over time the current standard of care corticosteroids (prednisone, deflazacort).
- In the **US, Agamree was recently approved** for the treatment of DMD for patients aged 2 years or older. In **EU**, we expect **marketing authorization on Dec 18, 2023,** following the positive CHMP opinion issued in October. **Commercial launch** is planned to take place in **Q1-24E in the US** by partner Catalyst and by Santhera in **Q1-24E in Germany**, followed by the UK in early Q3-24E, and later in other core EU markets.
- In **EU, Agamree's differentiated label** (for safety) should help to drive market share gains, thus facilitating switching despite a higher price point. The US label is similar to the steroid deflazacort (Emflaza, FDA-approved for DMD) but we see **strong demand** from parents, patient advocacy groups, and DMD specialists to drive Agamree uptake.
- Vamorolone has the potential to be developed in a range of **other indications** as an alternative to corticosteroids ("pipeline in a product").

Agamree is FDA-approved in DMD and received a positive CHMP opinion

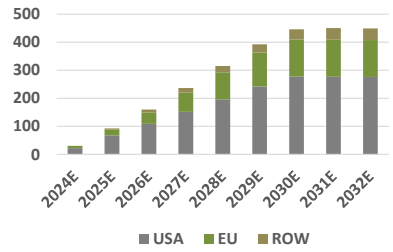
Source: Santhera, Catalyst Pharmaceuticals

Growth & Profits

- We estimate a global peak sales potential of CHF 450m for Agamree in DMD. In **Western EU** (where Santhera has a direct specialist sales force), we estimate **peak sales of CHF 132m** (2030E). We project **CHF 278m peak sales in the US** (2030E), resulting in an estimated CHF 32m royalty income. In China, vamorolone is partnered with Sperogenix.
- At peak, we estimate Agamree to have a **patient share** (as a % of steroid users) of **45% in the US, and 50% in EU**. As a proxy, Emflaza, approved in 2017, generates ~USD 250m net sales (2023E, US only) and has an estimated market share of ~50%. We include an ASP of 85k in the US (a slight discount to Emflaza) and EUR 30k in EU in our model.
- We estimate an EBITDA of CHF -22m in 2024E. With growing contributions from direct sales and licensing income, we see the **cash burn gradually diminish** and EBITDA turning positive by 2026E.
- The DMD market is well-defined and concentrated, with a limited number of expert centers. This should allow for a **targeted sales approach** and overall high profitability levels. Orphan drug protection and IP should provide **exclusivity at least until 2035E (EU) and 2040E (US).**

We see global peak sales of CHF 450m. Santhera expects >EUR 150m sales in Western EU in 5 years, slightly above OctE

OctE sales estimates for Agamree (CHF m)



Source: Octavian estimates

Cash Flow, Balance Sheet, Funding

- We estimate Santhera to become profitable in 2026E. With an estimated cash position of CHF 29m (end-23E), **the company is funded into early Q1-25E.** This does not include the payback/refinancing of Santhera's convertible bonds maturing in Aug 2024. We assume redemption of the CHF 13.5m listed CB, and conversion of the CHF 12m private CBs.
- Until break even, we estimate **cash injections totaling CHF 50m**. This estimate covers operational expenses, milestone payments (USD 20m in 2025E), and the redemption of the '24 public CB. To reflect the

Estimated cash burn and liquidity

OctE	2024E	2025E	2026E
Cash (Jan 1)	**28.8**	**14.4**	**8.3**
- Operating cash burn	-25.8	-13.1	1.1
- Cash out for milestone	0.0	-18.0	0.0
- Conv. Debt payback	-13.5	0.0	0.0
+ Equity Increase	25.0	25.0	0.0
Cash (Dec 31)	**14.4**	**8.3**	**9.4**

Source: Octavian

potential dilution, we base our rNPV model on a share count of 20.5m (fully diluted), vs. outstanding shares of 10.6m (excl. 2.0m treasury shares). Note, that at least a part of this could also be funded via other measures (e.g., debt or royalty funding).

Competitive Position

Differentiated safety profile vs. other steroids; complementary to other DMD treatment approaches

- The **DMD market remains underserved** and despite the emergence of novel therapies, there is no cure available. **Corticosteroids, used currently by ~70% of patients, are a mainstay therapy** to improve muscle strength and function and delay disease progression. Steroid use is very common in young, ambulatory patients (OctE: at up to 95%), but less in non-ambulatory patients (OctE: ~45%) due to increased side effects.
- We expect **Agamree to directly compete with the standard of care steroids prednisone** (generic) and **deflazacort** (Emflaza® approved in the US). Agamree was shown to exhibit comparable efficacy but with longer-term (48-week) data suggesting **reduced side effects**, notably related to bone health, growth trajectory (stunting), and behavior.

Currently, gene therapy is not curative

- **Steroids are currently being used as a foundational therapy** on top of other treatments. Newer modalities, with different modes of action, include exon-skipping drugs and **gene therapy.** However, they also have limitations and will likely be used in combination with steroids.

Octavian vs. Consensus

- Given the limited coverage by sell-side analysts, there is currently **no consensus available** that we consider reliable.

Valuation & Rating

We derive a PT of CHF of 12 from our rNPV and initiate with a HOLD rating

- To derive our **PT of CHF 12** for Santhera, we use a **risk-adjusted Net Present Value** (rNPV) model. We include only revenues from vamorolone in DMD. Our sum-of-the-parts model provides detailed forecasts of vamorolone in key territories. We use probability-adjusted NPVs (2023-2038E), and a **discount rate of 15.0%** to reflect execution and market risks. **Agamree US contributes CHF 8.3/share** (at 100% probability) and **EU CHF 5.2/share** (at 90% probability) to our fair equity value of CHF 12.3. We take a conservative approach and currently attribute no value to the earlier-stage pipeline (lonodelestat, vamorolone in other indications). **We initiate coverage with a HOLD rating**.

rNPV (CHF M)	NPV (100%)	RISK ADJUSTMENT	rNPV	PER SHARE (CHF)	IN %
VAMOROLONE USA (IN DMD)	170	100%	**170**	**8.3**	67%
VAMOROLONE EU (IN DMD)	119	90%	**107**	**5.2**	42%
VAMOROLONE ROW (IN DMD)	25	80%	**20**	**1.0**	8%
VAMOROLONE IN OTHER INDICATIONS	0	0%	**0**	**0.0**	0%
LONODELESTAT (PHASE I)	0	0%	**0**	**0.0**	0%
OTHER INCOME/COST (ADJ.)	-81	100%	**-81**	**-3.9**	-32%
TOTAL PRODUCTS/COST	233		**216**	**10.5**	85%
NET CASH (as of end 2022)	1		1	0.1	1%
EXCHANGEABLE NOTES (repaid in H2-23)	-28		-28	-1.4	-11%
PUBLIC CONVERTIBLE DEBT ('24)	-14		-14	-0.7	-5%
CASH FROM OPTIONS/WARRANTS*	27		27	1.3	11%
ASSUMED CAPITAL INCREASES (2024E/25E)	50		50	2.4	20%
EQUITY FAIR VALUE	**270**		**253**	**12.3**	**100%**

NO. OF SHARES ISSUED (M)	*12.559*	*incl. treasury shares*	
TREASURY SHARES HELD	*1.995*	*(1.415m treasury shares used for Catalyst stake in Q3-23E)*	
CURRENT SHARES OUTSTANDING	***10.564***		
NEW SHARES FOR CONV. DEBT (2024) - private (HB)	*1.677*	*conversion price CHF 5.00-10.00*	
*NEW SHARES FOR WARRANTS**	*1.403*	*exercise price CHF 5.00-20.00*	
*NEW SHARES FROM OPTIONS**	*1.339*	*exercise price CHF 0.00-1'126*	
SUB-TOTAL	***14.983***	***fully diluted share count (excl. treasury shares)***	
NEW SHARES FOR CAPITAL INCREASES (2024E/25E)	*5.556*	*assumed funding requirements until break-even (calculated at CHF 9/share)*	
TOTAL NO. OF SHARES (M)	***20.538***	***used for rNPV calculation***	WACC: 15.0%
NEW SHARES FOR CONV. DEBT (2024) - public/listed	*0.452*	*conversion price CHF 30.3 - assume it will be redeemed - not included in share count*	

SOURCE: OCTAVIAN

*assumed avg. strike price of CHF 10

Sensitivity Analysis

- The following table shows the sensitivity of our rNPV model for various WACC assumptions (range 12.0-18.0%). Further, we also show the sensitivity to share dilutive effects related to our funding assumptions.

Sensitivity to WACC (%)							
	12.0	13.0	14.0	**15.0**	16.0	17.0	18.0
CHF	14.9	13.9	13.1	**12.3**	11.6	10.9	10.3

Sensitivity to share price used for dilution (capital increases):						
	7	8	**9**	10	11	Price (CHF)*
CHF	11.4	11.9	**12.3**	12.6	12.9	**rNPV per share**

*Assumed share price to calculate the no. of new shares

Main Investment Risks (non-conclusive list)

- Product-related: Agamree might not be approved for commercialization in the EU, UK, or other jurisdictions. Market uptake, the reimbursed price, or the competitive situation might differ from our expectations.
- Operational: The company, while having limited experience in commercializing products (except for Raxone in the indication LHON), intends to sell its lead product vamorolone in key EU markets via its direct sales teams. In the US, commercialization mostly depends on the abilities and performance of Catalyst Pharma.
- Financing: Based on the existing cash at hand and the gross cash burn rate, Santhera will require further funding to reach profitability.
- Liquidity: Santhera is a small cap with limited free float.

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Company Overview

Company Set-up, History

- Santhera Pharmaceuticals AG was founded in 2004 through the merger of Graffinity Pharmaceuticals (a German-based preclinical development company) and MyoContract. The latter had been founded by Dr. Thomas Meier (former CEO of Santhera from 2011-19, today a Board member) as a spin-off from the Biocenter Basel. The merged company went public in 2006, raising CHF 89m by issuing new shares at the IPO.

The earlier focus was on idebenone. The development in DMD was discontinued in 2019

- Santhera went through a difficult time after failing to get FDA approval for **its former lead asset idebenone (Puldysa) in DMD.** The company **discontinued the development** of Puldysa after an interim analysis of the US pivotal trial did not show efficacy in October 2020, and went through a restructuring. With CHF 60m convertible debt maturing in Feb 2022, there were limited options for funding. The subsequently issued exchangeable notes have since been restructured.
- **A new management team joined at the end of 2019**, with Dario Eklund assuming the role of CEO, and Andrew Smith taking up the role of CFO in April 2020.

Acquired rights to vamorolone in 2020

- In September 2020, **Santhera licensed worldwide rights for vamorolone** in DMD and all other indications from US-privately held Reveragen. Santhera completed the clinical development work in EU and US and **received FDA approval in October 2023 in DMD.**

The Raxone/LHON business was fully divested in July 2023

- In July 2023, Santhera **divested its entire idebenone** business in all indications, including the EU-approved Raxone for the rare eye disease Leber's Hereditary Optic Neuropathy (LHON), to **Chiesi**, an Italian-based research-focused healthcare group. The CHF 26m French reimbursement liability was transferred to Chiesi, which helped to improve the overall debt situation. Santhera retains a variable single-digit payment on net sales or milestone payments of up to USD 10m should Raxone for LHON ever be approved in the US. In addition, if Chiesi pursues Idebenone in non-ophthalmological indications, the company could be eligible for similar milestone payments and high single-digit royalties.
- The company is headquartered in Pratteln, near Basel, and employs currently 65-70 FTEs. As it has out-licensed the North American rights of vamorolone to Catalyst, **Santhera will focus on commercialization in key EU markets, expected to start in Q1-24E**.

Capital Structure and Funding

Share Capital ('000s)	
Shares Issued	12,559
Less: Shares held in Treasury	- 1,995
Shares Outstanding	10,564
Equity Linked Instruments	
CB '24 - listed (CP CHF 30.03)	452
CB '24 - private (CP CHF 5.00-10.00)	1,677
Warrants (CP CHF 5.00-20.00)	1,403
Options (CP CHF 0.00-1'126)	1,399
Total Shares Underlying EL-Instruments	4,931
Fully diluted "as if converted" share count	**15,495**

Source: Santhera *Note: we assume repayment (no conversion) of the listed CB '24, and include additional equity increases for the FD share count in our rNPV*

- After a challenging period with a continued shortage of funding, Santhera's capital structure was significantly strengthened through the **partnering transaction with Catalyst Pharmaceuticals** (USD 75m upfront in cash, USD 15m equity investment), which closed on July 19, 2023, and resulted in a **cash inflow of CHF 78.6m** to Santhera in H2-23 (net of transaction costs).
- Subsequently, Santhera **fully repaid the CHF 29m Exchangeable Notes** to Highbridge, significantly reducing its debt obligations.
- Upon FDA approval of Agamree in October 2023, Santhera received milestone payments totaling USD 36m from Catalyst, thereof USD 26m payable to Reveragen and Idorsia (sub-licensor), implying net **cash proceeds of USD 10m for Santhera in H2-23E** (~CHF 9m).

Through the Catalyst transaction, Santhera reduced its debt and extended its cash runway into Q1-25E

- The company's current guidance is a **cash runway into Q1-25E**.
- Santhera still has **CHF 13.5m and CHF 11.8m of aggregate principal amount of '24 public and private convertible bonds** outstanding.

Shareholders

- **Catalyst (11.2%)** and **Idorsia (10.3%)** are Santhera's major shareholders. Highbridge Capital, even after the repayment of the Exchangeable Notes, remains a significant holder of the convertible bonds.

Board of Directors

- **Thomas Meier**, Chairman, Non-Executive. Founder, and CEO for several years. University of Colorado Health Science Center, Biocenter/ University of Basel. Viopas Venture. Board member Visgen, Novaremed.
- **Philipp Gutzwiller**, Audit & Compliance Commitee. Managing Director at Mizuho Bank responsible for Consumer and Healthcare clients.
- **Bradley C. Meyer**, Compensation Committee. Founded Ducera Partners, Millstein & Co has a Financial & M&A background. Helped restructure Houlihan Lokey. Board: Aveng Group, Quotient.
- **Otto Schwarz**, Former COO of Actelion. Pharmacist with PhD from University of Vienna. Board Member of Altana Pharma (2004-08). 16 years at Schering-Plough, 4y at Eli Lilly. Board: Stalicla. Advisor: Idorsia.

Executive Management

- **Dario Eklund**, 1968, CEO since Dec 2019. Previously COO of Vifor Pharma, Board member of Vifor's JV with Fresenius Medical Care, and a member of the Executive Committee at US-listed Organogenesis.
- **Andrew Smith**, 1962, CFO since Apr 2020. Previously, he was CFO and COO at Allecra Therapeutics and CFO of Sucampo Pharmaceuticals (Nasdaq-listed). Board member of UK-listed Arix Bioscience (LSE: ARIX).
- **Shabir Hasam**, 1970, Chief Medical Officer since May 2022. Joined Santhera in 2015. Prior at Novartis, including EU Medical Director & Global Ass. Brand Director for Neuroscience franchise and SMM Oncology.
- **Marc Schrader**, Chief Technology Officer as of Jan 2024. With Santhera since 2022; before that, he was at Tillolots Pharma, Actelion, and Janssen/Johnson & Johnson.
- **Oliver Strub,** 1963, General Counsel & Secretary to the Board, EVP. He joined in 2006 as General Counsel. Before that, he was at Ciba Geigy.
- **Gert Jan van Daal**, Chief Commercial Officer as of Jan 2024. Joined Santhera in 2015. Previously, he held positions at Serono, Acteliion, and Intermune.

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Duchenne Muscular Dystrophy

DMD is a rare, incurable disease with a high unmet medical need

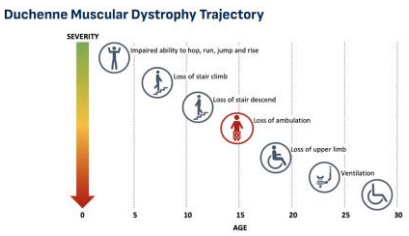
- **DMD is the most frequent form of muscular dystrophy.** It is caused by **mutations in the dystrophin gene** that cause an almost complete lack of the dystrophin protein in the patient. DMD has an estimated incidence of 1:3'500 to 1:5'000. The **DMD patient population in the US and EU combined is ~30'000 to 35'000**.

30'000–35'000 DMD patients in the US and EU combined, thereof ~70% using steroids

- Muscular dystrophies are a clinically and pathogenically heterogeneous group of muscular diseases varying in the age of onset, involved muscles, and severity, leading to progressive degeneration of muscle fibers. All of them are rare diseases. Another type of MD is **Becker muscular dystrophy (BMD),** which affects the same gene as in DMD but is characterized by milder symptoms (incidence 3:100'000).

Symptoms and Pathogenesis

DMD disease progression trajectory

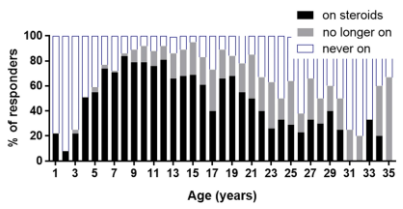


Source: Caprocor

- DMD and BMD are X-chromosome-linked diseases, affecting almost exclusively boys. The disease is caused by mutations in the gene coding for dystrophin protein, which as a consequence **results in a lack (in the case of DMD) or a shorter (BDM) dystrophin protein**. This protein is essential for the maintenance of muscle cell integrity. Without dystrophin, normal activity causes excessive damage to muscle cells, and over time is replaced with fat and fibrotic tissue, losing function.
- **Diagnosis occurs in early childhood,** typically latest by age 5. Affected boys have slow motor development and show certain characteristics, e.g. the Gower's sign (holding on their knees with hands and arms when standing up). **The disease is progressive and causes weakness in the skeletal, diaphragm, and cardiac muscles**. Ambulation (the ability to walk) is usually lost in the early teens. The development of palliative therapies, including night-time assisted ventilation and cough assistance, heart failure medications, and corticosteroids, has extended the average life span to up to 40 years. Eventually, patients die of cardiac complications or respiratory illnesses.

Steroids in the Treatment of DMD

Trends in corticosteroid use in DMD (US Duchenne Registry, 2007–2016)



Source: BMC Neurology (2019)19:84

- **Glucocorticosteroids** are effective anti-inflammatory agents and the current standard of care in DMD, delaying the course of the disease (disease-modifying). **Prednisone (off-label) and deflazacort** (Emflaza, approved in the US) have been utilized for decades; we describe them in more detail on page 14/15. Early initiation of steroid therapy was reported to delay the time to loss of functional milestones by 2-3 years.
- Current clinical guidelines **strongly recommend** the use of **prednisone** or **deflazacort** in children with DMD **when motor development stalls or starts to decline.** Treatment is recommended throughout life.

Corticosteroids delay disease progression by 2–3 years but are associated with side effects, limiting their (long-term) use

- **Steroid therapy is usually initiated around 4-5 years of age** to slow the decline in muscle strength and function regardless of the genetic mutation. However, their **long-term use is hampered by side effects** (e.g. weight gain, cushingoid features, behavioral problems, stunted growth, and increased rate of fractures amongst others) that often result in **down-titration to subtherapeutic** doses to manage tolerability issues and **eventually premature discontinuation of treatment**.
- US guidelines recommend prednisone 0.75mg/kg/day as the optimal dose, backed by "moderate evidence". Weight gain and cushingoid

appearance may occur more frequently with prednisone, but cataracts are more frequently reported with deflazacort, as stated in the US/AAN guidelines (last updated in 2016 and reaffirmed in Jan 2022). Alternate dosing regimens include high-dose weekend steroids or 10 days on/off dosing. Especially after **the early teenage years** (which often corresponds with loss of ambulation), **many patients discontinue the use of steroids given these adverse events.** Hence, there is a medical need for a treatment providing steroidal efficacy with a more benign tolerability and safety profile.

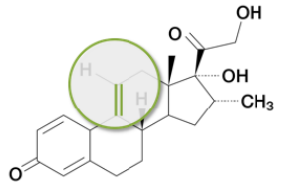
Agamree (vamorolone) in DMD

Mode of Action

Agamree is a novel steroid-class treatment option with a differentiated safety profile

- **Vamorolone**, originally developed by privately-held Reveragen, is a **small molecule "dissociative" delta-9, 11 glucocorticoid analog**, targeting the glucocorticoid receptor (GR; also known as NR3C1). The structure and mode of action are overall similar to corticosteroids, but the subtle difference in the chemical structure leads to different ("dissociative") properties.
- Steroid drugs, when binding to the GR, activate the receptor. In consequence, the activated GR complex up-regulates the expression of anti-inflammatory proteins in the nucleus or represses the expression of pro-inflammatory proteins in the cytosol, thus displaying **potent anti-inflammatory properties**.

Structure of Vamorolone



Source: Santhera

- Anti-inflammatory drugs of the corticosteroid class show a carbonyl (=O) or hydroxyl (-OH) group on the C11 carbon of the steroid backbone. In contrast, **vamorolone contains a double bond between the C9 and C11 carbons** (see left, in green). This change in structure has been shown to remove a molecular contact site with the glucocorticoid receptor, impacting the receptor binding and altering the enzyme and membrane interactions, and ultimately, being thought to be responsible for an improved side effect profile. **Importantly, the anti-inflammatory action is maintained, with the retained inhibition of NF-κB pro-inflammatory transcription factors.**

Agamree has the same anti-inflammatory effects but less unwanted side effects

- This is thought to be the **main difference vs. prednisone and deflazacort**, which activate the mineralocorticoid receptors in addition to the GC receptors, which may play a role in a wide range of adverse effects. Steroids are seen as a mainstay in DMD and hence, **any modulation to improve secondary effects should be received well by treating physicians and patients**.

Clinical Development and Clinical Data

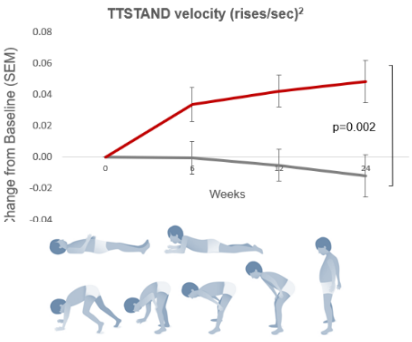
Agamree is FDA-approved and should soon receive EU approval

- **Approval was based on the Phase IIb VISION-DMD study**, a double-blind pivotal study designed to demonstrate the efficacy and safety of vamorolone compared to placebo and prednisone (active control) in DMD. The study was conducted in 33 centers in 11 countries.

The pivotal study evaluated vamorolone vs. placebo & prednisone (active control) over 24 weeks (for US filing) and 48 weeks (required by the EMA)

- **In the first 24 weeks (period 1), 121 ambulant boys aged 4 to <7 years** were randomized to receive vamorolone (2 or 6mg/kg/day), prednisone (0.75mg/kg/day), or placebo. **114 patients continued for another 24 weeks (period 2).** Those on vamorolone (2 or 6mg/kg/day) continued on these doses, while those on prednisone and placebo were randomized to receive vamorolone 2 or 6mg/kg/day (after a 4-week tapering period). 112 subjects completed the study.

The 1° endpoint at 24 weeks was met

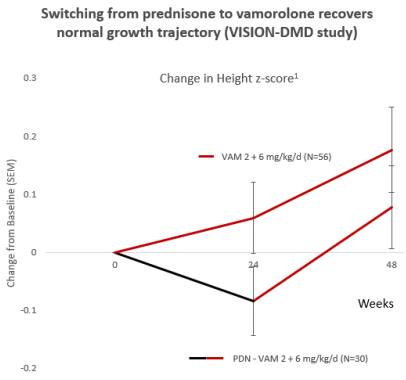


Rise time (sec)²	BL	w 24	% Change
VAM 6 mg/kg/d	6.0	4.6	- 23%
Placebo	5.4	5.5	+ 2%

Source: Santhera

Long-term efficacy of vamorolone 6mg/kg/day was comparable to SOC steroids at 48 weeks

Switching from prednisone to vamorolone recovers normal growth trajectory



Source: Santhera

Positive CHMP opinion on Oct 13, 2023, EMA & UK approval anticipated in Dec-23E

- While the FDA only considered the 24-week data for approval and focused on efficacy vs. placebo, period 2 was added upon the request of the EMA. **This is important because as a consequence, the FDA label is only based on the 24-week data**, and hence, excludes the effects seen in period 2.
- In June 2021, 24-week topline data of VISION-DMD was released. **Vamorolone 6mg/kg/day met the primary endpoint TTSTAND (time to stand velocity) versus placebo after 24 weeks** (p-value of 0.002). There was a 23% improvement in time-to-stand velocity by patients treated with vamorolone 6mg/kg/day. Consistent results across multiple secondary endpoints support the results of the primary EP, and the relative efficacy of vamorolone 6 mg/kg/day was comparable to prednisone across primary and secondary efficacy endpoints (including 6MWT/6-minute walk test; TTRW/ time to run/walk 10m).
- **Vamorolone was generally safe and well tolerated**. The most commonly reported adverse events vs. placebo in the 24-week VISION-DMD study were cushingoid features, vomiting, and vitamin D deficiency. Adverse events were generally mild to moderate.
- Importantly**, vamorolone showed no negative impact on bone biomarkers,** supporting the potential for long-term bone health in contracts to classical steroids.
- Primary safety and efficacy analysis of the 24-week VISION-DMD study was published in **JAMA Neurology** on September 1, 2022 (link); it was noted that in the study, vamorolone was able to reduce bone morbidities while retaining efficacy. Furthermore, the proven efficacy over a broad dose range (2-6mg/kg per day) may enable physicians to adjust dose based on clinical observations and patient preferences
- In November 2021, the **48-week read-out** was announced. In the study, a group of patients was switched from prednisone to vamorolone (after week 24; period 2). Vamorolone 6mg/kg/day showed maintenance of efficacy across all parameters until the end of the study at week 48. Further, it was shown that **vamorolone did not stunt growth,** and **switching from prednisone to vamorolone (6mg/kg/day) recovered the normal growth trajectory.**
- Santhera was able to use **12-months prednisone data** (from the 4-DMD study, an external comparator study with 196 patients), allowing for a comparison with vamorolone 12 months treatment; note that this dataset was part of the EMA submission and hence, Santhera expects it to be included as part of the label.
- Subsequently, Santhera prepared for regulatory submission, but the FDA filing was delayed due to issues at a third-party manufacturer. The NDA package was finally accepted by the FDA in February 2023, with a PDUFA date set for October 26, 2023, and approval was granted.
- **A positive CHMP opinion** (link) was issued on October 13, 2023, recommending the granting of an EMA marketing authorization and acknowledging the **positive benefit-risk profile of Agamree in boys 4 years and older.** We think that **formal EMA marketing authorization** will be issued before year-end (most likely on December 18, 2023).
- We understand that the **EMA label will include certain safety benefits vs. corticosteroids**. In addition to VISION-DMD (48 weeks), the opinion

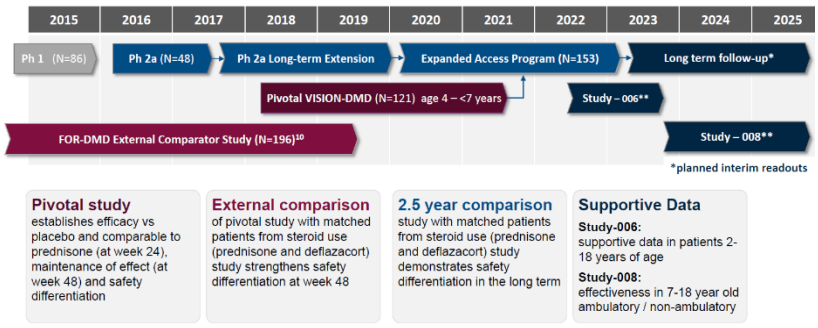
was derived from clinical evidence from 3 open-label studies (including extensions), in which vamorolone was administered at doses between 2 and 6 mg/kg/day for a total treatment period of up to 30 months, and external comparator study (FOR-DMD). Santhera plans to file in 2025E for a variation in the label to include boys 2-4 years old.

The US label is broad but not much differentiated. However, we assume the DMD community to be well aware of the benefits

- **The FDA label** (link) **is broad but not differentiated vs. other corticosteroids.** Overall, it is **similar to Emflaza's label** (also concerning steroid-class-related side effects). Agamree (which comes as an oral suspension of 40mg/ml) is indicated for **boys 2 years and older**, with a **recommended dose of 6mg/kg/day**. Given that the FDA was looking solely at the 24-week data, it contains no additional longer-term data from Vision-DMD. Still, we would expect the **DMD community to be well aware of the clinical data supporting a more differentiated safety profile of Agamree**. While Catalyst can make use of the 48-week data, they must refrain from making claims that contradict the label.

A Phase IV program is ongoing to gather more data to support the differentiation and establish Agamree as the new SOC

- **Post-marketing (Phase IV) studies are underway to generate further supportive data.** The aim is to investigate vamorolone in a broader DMD patient age group, as the clinical development program until now included boys 4 to >7 years old. As part of the pediatric investigational plan required by the EMA, a Phase II (study 006; 20-25 patients) study aimed at collecting information on vamorolone outside this age range through the inclusion of boys starting at 2 and up to 18 years. **The read-out of study 006 is expected in H2-24E.** Another previously planned study (008) to evaluate the effectiveness of vamorolone in patients aged 7-18 years (both ambulatory and non-ambulatory) is now unlikely to start, given the broad label with no upper age restriction.



Source: Santhera company presentation

- Furthermore, **long-term follow-up data from the expanded access program (with 153 patients)** is still ongoing and is planned to last until end-25E. We understand that currently, 80-100 boys thereof have been using vamorolone for 5-7 years. A first interim data read-out is anticipated at end-24E (with hard clinical endpoints vs. prednisone).
- In conclusion, we see Agamree as a **promising new therapeutic option for DMD patients**, with a more benign long-term safety profile.

Ongoing Phase II study in BMD (Becker's Muscular Dystrophy)

- Separately, a second **Phase II pilot study in BMD** (Becker muscular dystrophy) is evaluating the safety, tolerability, and exploratory clinical efficacy on motor function outcomes of vamorolone vs. placebo in males aged between 18 and 65 years. The read-out is expected in Q1-25E.
- Currently, only ~20% of BMD patients are using steroids (vs. ~70% in DMD) on the back of a less favorable risk-benefit ratio. Further, the

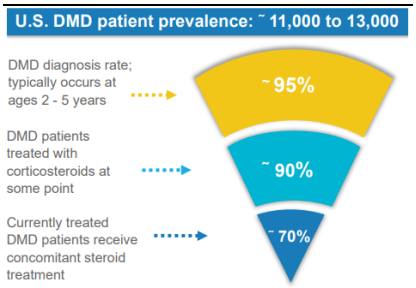
prevalence of the disease is lower than DMD (~1/3). Given these considerations, we see the opportunity in BMD as considerably smaller. Also, we currently **do not include it in our model**.

Reimbursement

Payor access could be challenging, but demand from parents and physicians should support uptake

- In the US, Emflaza requires **prior authorization**, requiring the patient to try the lower-cost prednisone before switching to Emflaza ("step edit"). For Agamree, we assume the same mechanism (second-line treatment) in our base case. We understand, however, that administrative hurdles for physicians are well manageable and should thus not prevent widespread use of an improved steroid-class drug such as Agamree.
- **In EU countries, we see a reimbursement risk**. Agamree will first be launched in Germany, followed by the UK. We think a price point of ~30-40% of the US price is a reasonable assumption, and Agamree's differentiated label in the EU should allow for a steep premium price against the generic steroids. In Q2-24E (May), NICE is expected to make vamorolone available on the NHS and set a reimbursed price. In Germany, the usual process allows for free pricing in the first 6 months, with negotiations taking place thereafter (i.e., early Q3-24E). The final negotiated price will be set after 1 year.

Agamree Sales Projections



Source: Catalyst Pharmaceuticals

- **Patient pool:** It is estimated that there are **~11-13'000 DMD patients in the US** (prevalence), thereof ~90% are using steroids at some point in time. An estimated **~70% of diagnosed and treated patients are currently on (concomitant) steroid therapy**. Hence, we estimate the eligible population for Agamree treatment is ~8.5k patients in the US. In EU4, the UK, and other markets where Santhera will market Agamree by themselves, we estimate a similar DMD population (~12k, thereof ~8.5k taking steroids) and another ~10-12k in the rest of EU/ROW.
- **Market share:** In our forecast model (base case), we assume a **penetration rate in steroid users** (all age groups) of **45% (US)** and **50% (EU)** at peak. Moreover, we assume that Agamree can make some inroads into young children not currently using steroids due to side effects.

Pricing in the EU is not determined yet. We base our forecasts on a net ASP of EUR 30'000/patient p.a., well below the US price (OctE: USD 85'000)

- **Pricing**: We use a **net ASP** of **USD 85k/patient p.a. in the US** (~5% discount to Emflaza) and **EUR 30k in EU** (which could be somewhat conservative). We use a (high) compliance rate of 85% but remain conservative by not assuming a higher average patient weight over time.
- On these assumptions, we forecast Agamree **peak sales of CHF 132m in EU, and CHF 278m in US** (booked by partner Catalyst). **Globally**, we project a peak sales potential of **CHF 450m** (2031E). **The company guides for >EUR 150m after 5 years (in core EU).** Our somewhat lower estimate (CHF 132m by 2030E) is likely due to a slightly delayed ramp-up and a lower ASP (to reflect potential reimbursement challenges).
- **Upside risk:** The forecasted market share could become bigger if guidelines were adapted to prioritize Agamree therapy over prednisone and deflazacort. At this stage, we do not include this in our estimates, as more data might be needed to claim long-term benefits.
- **Downside risk:** As the reimbursed price is not yet set, revenues could be lower than forecasted. Note, that the potential impact of novel treatments such as gene therapy, possibly leading to a reduction of overall steroid use, is not reflected in our model, presenting a (mid-term) risk.

Treatment Landscape in DMD

Steroids are a foundational therapy, used in combination with exon-skipping drugs and gene therapy

- We analyzed other available therapeutic options and pipeline candidates in DMD. Next to steroids, approved treatment approaches for DMD include (1) **exon skipping** and **nonsense read-through agents**, and (2) more recently, **gene therapy (Elevidys)**. Further, we note the potentially soon-to-be-approved drug candidate **givinostat**, an anti-fibrotic that was given on top of SOC in clinical trials.
- In our view, all these therapies are **complementary and will not directly compete with vamorolone**. We believe glucocorticosteroids will **continue to be used as a backbone/foundational therapy**, and **vamorolone is positioned as a safer alternative** to today's SOC prednisone and deflazacort. Agamree's value proposition includes (1) durable efficacy comparable to SOC, (2) preserved bone health, (3) improved safety profile vs. prednisone, and (4) a 3-fold dose range with a dose-dependent safety profile, to enable optimal long-term treatment.
- In general, it seems that drug development activity in DMD has picked up in recent years. The wide variety of therapies currently approved or in development, ranging from gene therapies to small molecules, likely reflects the growing belief in a **multi-pronged approach to DMD treatment.** We summarize the currently approved and most clinically advanced drug candidates for the treatment of DMD in the table below and describe some of them in more detail on the following pages.

Emflaza (deflazacort)

Emflaza received FDA approval in 2017. 2023E sales are estimated at ~USD 250m

- Below we describe in more detail the **two steroids used today, prednisone and deflazacort**. In our view, **the main "proxy" and initial target group for Agamree switches will likely be Emflaza in the US**.
- **Emflaza (deflazacort) has been approved in the US for the treatment of DMD since 2017**. It is an old drug that was repurposed and brought to the market by PTC Therapeutics (PTCT, NR), which bought it from Marathon for USD 140m after a controversy over the intended price tag. Emflaza was initially approved in February 2017 for DMD patients 5 years of age or older, and in June 2019, a label expansion was granted (encompassing also children aged 2-5 years). Emflaza is a pro-drug that is converted by the body into an active metabolite (21-desDFZ), that helps to decrease inflammation and suppress the immune system.
- **Approval was based on a 196-patient Phase III study** (that was already completed in 1995), comparing the efficacy and safety of deflazacort vs. prednisone and placebo. The double-blind, randomized, placebo-controlled, multicenter study evaluated muscle strength among 196 boys aged 5 to 15 years with DMD for 52 weeks. After 12 weeks of treatment, patients taking EMFLAZA had significantly improved muscle strength vs. placebo (0.15 change in strength score vs -0.10 change in strength score). It was also found that deflazacort was associated with less weight gain than prednisone.

Emflaza's net ASP in the US is estimated at USD 80-90k p.a. for a boy weighing 25kg

- Available as a tablet (in 4 strengths) or as an oral suspension, the recommended dosage is ~0.9mg/kg/day once daily. For a boy with a weight of 25-30g, this is equivalent to ~22-27mg/day. After a series of price hikes since launch, we estimate the current ASP for a daily dose of 24mg/day is ~USD 430, or USD 13k/month (source: drugs.com). Assuming 100% compliance, we calculate a "theoretical" ASP of ~USD 155k

p.a. for a boy with a weight of 25-30kg for Emflaza. In the real world, the **average gross ASP is estimated at ~USD 130k p.a. On a net basis (gross-to-net adjustment of ~30%),** this equates to annual costs of **~USD 90k** on average. For older patients, the corresponding costs are accordingly higher, reaching up to USD 200k p.a.

Emflaza has an estimated share of ~50% in the US (steroid users)

- Assuming a compliance rate of 60-70% for Emflaza, it suggests that >4'000 DMD patients are using Emflaza currently in the US. Out of an estimated prevalence of >12k and thereof 70% on steroids (~8.5k), we derive a **market share of up to 50% for Emflaza in the US**, with the remaining ~50% of patients using prednisone.
- Emflaza has no IP protection but **7 years of orphan drug exclusivity in the US, which will expire in Feb-24E** (for patients >5 years) and in June-26E (for patients 2-5 years).

Emflaza Annual Net Sales Since Launch

2017	2018	2019	2020	2021	2022	2023E
29	92	101	139	187	218	250
NA	*217%*	*10%*	*38%*	*35%*	*17%*	*15%*

Source: Octavian, PTC Therapeutics

Future revenues are expected to decline, as Emflaza will lose exclusivity in 2024E

- **Emflaza generated net sales of USD 218m in 2022,** +17% yoy, and we estimate sales to grow to **~USD 250m in 2023E.** Growth is driven by new patient starts, broader access, continued high compliance, and appropriate weight-based dosing, but we assume also by higher pricing. However, with the product losing orphan drug exclusivity in 2024E, we expect sales to decline (Bloomberg consensus 2024E: USD 172m).
- **In EU,** unlike the US, Emflaza/deflazacort was never approved but is used off-label. The estimated share is not known but prednisone is the most used steroid in DMD. Like prednisone, deflazacort is generic and comes at low prices (we estimate ~EUR 0.60/pill, or >EUR 200 per year).

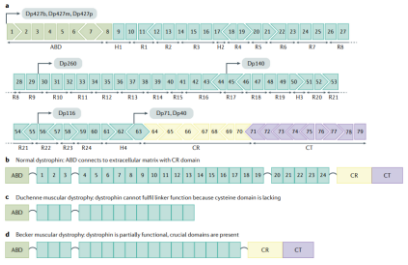
Prednisone

Prednisone is generic and the most commonly used steroid in DMD patients, particularly in EU

- **In contrast, prednisone (prednisolone) is highly genericized and therapy is affordable.** The drug was FDA-approved in 1955 and is being used in a multitude of diseases related to the immune system, and inflammatory processes (e.g., rheumatic diseases, asthma). Prednisone is converted in the liver into prednisolone. Its use in DMD is off-label.
- In DMD, Prednisone is usually used in patients 4 years and older in whom muscle function is declining or plateauing. It is recommended at a dosage of 0.75 mg/kg per day. Pricing varies; for a monthly supply, costs can be as low as ~USD 10-15/month, or ~USD 120-180 for a year, but at a maximum of ~USD 1'500 per year for branded versions.

Gene-directed Approaches

Schematic depiction of dystrophin protein



Source: Nature Reviews, Disease Primers, article citation ID: (2021)7:13

- The dystrophin gene is very large and makes up ~0.1% of the human genome. It is located on the X chromosome and is composed of **79 exons** and 8 promoter regions. An estimated 60-70% of mutations in DMD patients are deletions, while duplications of 1 or several exons correspond to 5-15%, and point mutations, small deletions, or insertions for 20%. Most deletions occur between the exons 44 and 55.
- If these mutations **alter the reading frame of dystrophin** (out-of-frame-mutation), **the protein formation is prematurely truncated and the resulting protein is not functional;** the patient develops DMD. If the mutation is "in frame" and hence, the protein production machinery is not stopped, the dystrophin is smaller in size but still functional as it still contains the crucial binding domains. In this case, the patient is diagnosed with Becker's muscular dystrophy (BMD). This observation served as the basis for the development of exon-skipping therapies.

Exon-skipping Therapies

Exon-skipping therapies work only for a minority of patients and can only delay (but not stop) the disease

- Discovered >25 years ago, exon skipping relies on **modifying the splicing process of the mRNA to restore the disrupted reading frame**. It uses **antisense oligonucleotides** (ASOs) to hide one or more exons to re-establish the open frame and produce a functional protein.
- Exon skipping drugs have several drawbacks: (1) They can be used only for specific DMD sub-populations (in total for ~1/3 of patients), (2) exon skipping can only restore the reading frame but without fixing the gene, and (3) it requires repeat (weekly) administration. Consequently, the produced dystrophin protein is not normal but similar to the one produced by BMD patients. Hence, this drug class is no cure for the disease. Importantly, in clinical trials and clinical practice, **steroids are being used in combination with exon-skipping drugs.**

Nonsense Read-through Therapies

Translarna will likely be withdrawn from the EU market due to lack of efficacy; in the US, it was never approved

- This approach uses agents that allow the protein synthesis machinery to recognize and skip the "false" stop signal generated by a mutation. **Nonsense mutations make up 10-15% of DMD cases**. PTC's Translarna (ataluren) failed to get approved in the US but got conditional marketing authorization from the EMA in 2014 for ambulatory DMD patients >5 years with a nonsense mutation. However, after a negative opinion issued by the CHMP, it could potentially be withdrawn from the market; a decision is expected in Q1-24E.

Gene Therapy: Sarepta/Roche at the Forefront

Gene therapy aims to restore expression of a (shortened) dystrophin gene, possibly decreasing the severity of the disease

- **Elevidys** (delandistrogene moxeparvovec-rokl) is **a viral vector-based gene therapy.** It is designed to deliver a micro-dystrophin-encoding gene directly to the skeletal and cardiac muscle to enable a durable clinical response. It is the first gene therapy approved in DMD.

Elevidys micro-dystrophin expression in studies 1 and 2 (Western Blot Assay)

Western blot (% of ELEVIDYS micro-dystrophin compared to control)	Study 1 (Week 12) Part 1 (n = 6)	Study 1 (Week 12) Part 2 (n=21)	Study 2 (Week 12) Cohort 1 (n = 20)
Mean change from baseline (SD)	43.4 (48.6)	40.7 (32.3)	54.2 (42.6)
Median change from baseline (Min, Max)	24.3 (1.6, 116.3)	40.8 (0.0, 92.0)	50.6 (4.8, 153.9)

[a] All patients received 1.33 x 10^{14} vg/kg, as measured by ddPCR
[b] Muscle biopsies were obtained from the gastrocnemius
[c] Change from baseline was statistically significant
[d] Adjusted for muscle content. Control was level of wild-type (normal) dystrophin in normal muscle.

Source: Elevidys prescribing information (2023

- **The mode of action addresses the underlying cause of the disease.** It uses a non-replicating, recombinant, adeno-associated virus serotype rh74-based vector containing a micro-dystrophin transgene under the control of the MHCK7 promoter. The protein expressed is a shortened version (138 kDa, vs. 427 kDa size in normal muscle cells). In 61 subjects who received Elevidys, muscle biopsy analyses confirmed micro-dystrophin expression in skeletal muscle (primary objective of studies 1&2). For boys aged 4-5 years who received 1.33×1014vg/kg, the mean (SD) expression levels (change from baseline) at Week 12 were 95.7% (n=3) in study 1 (parts 1&2) and 51.7% (n=11) in study 2 cohort 1.

Elevidys is currently approved in the US for ambulant boys aged 4-7 years

- On June 22, 2023, the FDA granted **accelerated approval for Elevidys for the treatment of ambulatory children aged 4-5 years old** (independent of the specific mutation). Accelerated approval allows for drugs to be approved based on a **marker** (surrogate endpoint) that is considered reasonably likely to predict a clinical benefit. In the case of Elevidys, **micro-dystrophin was increased in the age sub-group 4-5 years**, as discussed above. A clinical benefit of Elevidys, including improved motor function, has not been established, and verification of a clinical benefit may be needed for full approval.

Sarepta will file for a label expansion of Elevidys. A decision is expected in 2024E

- **End of October 2023**, it was announced that the **pivotal study** EMBARK 3 (n=125, 4-7 years of age) **failed on the primary endpoint** NSAA (North Staar Ambulatory Assessment, a measure of motor function). However, clinically meaningful effects were seen across all secondary endpoints, and Sarepta plans to submit an efficacy supplement to the

BLA to get a label extension to treat all DMD patients and to convert the conditional into full approval. The FDA has indicated openness to consider the totality of evidence; a **decision is likely in 2024E**.

- A Phase III (ENVISION) study is underway, enrolling 148 patients (ambulant & non-ambulatory up to 18 years). The read-out is likely in 2026/27E. It includes Part 1 (72-week, randomized, double-blind, placebo-controlled), followed by Part 2 (patients who received placebo in Part 1 will be treated with Elevidys, and vice versa). Note, that all patients are on a stable dose of corticosteroids.

Limitations of gene therapy include re-dosing (currently not possible), and the expressed protein is only semifunctional

- It remains to be seen how **durable the treatment will be.** Currently, **gene therapy cannot be re-dosed** (as antibodies develop), and when the child grows, its effects might become diluted. On safety, the label carries warnings for severe liver injury, amongst others. Overall, we do not anticipate that **more widespread use of gene therapy will make steroid use obsolete, however, it could result in a lower steroid dosing**. At this stage, we keep the dosing of vamorolone roughly stable in our model, given its more benign side-effect profile.
- **Elevidys is a single-dose infusion and is priced at ~USD 3.2m (wholesale acquisition price), or an estimated ~USD 2.4m (net)** per patient, making it one of the most expensive drugs in the world. The recommended dose of ELEVIDYS is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight. For a boy with a weight of ~20kg, it requires 20 vials of product. **Global peak sales are currently estimated at ~USD 5.6bn by 2029E** (source: Globaldata).
- **Sarepta Therapeutics** developed and manufactures Elevidys and commercializes the product in the US. In Dec 2019, **Roche partnered with Sarepta for ex-US territories**, paying USD 1.15bn upfront, up to USD 1.7bn milestone-based payments, and royalties on net sales.
- **Pfizer** has also a gene therapy (PF-06939926) in Phase III, with **final data anticipated in H2-24E.**

Givinostat

Givinostat has anti-fibrotic properties and is complementary to steroid therapy

- **Givinostat,** developed by privately-held Italfarmaco (based in Milan/Italy), is an **inhibitor of histone deacetylase (HDAC).** These enzymes become overly active in people with DMD, contributing to muscle weakness and wasting. By blocking HDAC, givinostat is expected to switch genes back on, including the FST gene, which codes for follistatin. This protein is expected to help build muscle mass while preventing fat and scar tissue from accumulating, thus easing muscle repair. The exact mode of action of givinostat is unclear, but similar to steroids, it works independently of the underlying mutation in the DMD gene, making it potentially suitable for a broad spectrum of younger and older patients.

Givinostat has a PDUFA date of Dec 21, 2023 (priority review)

- Givinostat was under priority review by the FDA, with a **PDUFA date of December 21, 2023**. In the EU, the filing was submitted in September 2023, with an **EMA approval possibly in H2-24E**. The filings were largely based on results from the Phase III trial that tested givinostat against placebo in **179 ambulant boys with DMD** (6-17 years, on average 9 years) over 18 months. Results showed that treatment significantly slowed motor function decline. Note, that all patients were on **concomitant Emflaza therapy**. Hence, we expect it to be used in combination with steroids. Givinostat is also in development for BMD.

OCTAVIAN

DMD Treatment Landscape (Overview)

Company	Generic name	Name	Description	Administration	Regulatory status	Comments
Anti-inflammatory (steroid class)						
Various suppliers	**prednisone**	**Deltasone Liquid Pred, etc.**	Glucosteroid	oral, daily	**Initially FDA approved 1955 off-label used in DMD**	Cheap generic, ~50% share in US. In EU SOC Dosage range 0.75 to 1.5mg/kg/day
PTC Therapeutics	**deflazacort**	**Emflaza (US)** **generic/off-label**	Glucosteroid Oxazoline derivative of prednisolone	oral, daily	**Approved (USA) Feb-2017** LOE in 2024E	US price raised to ~USD 130k/net ~USD 90k For >2 years, FDA-approved dose: 0.9 mg/kg/day ~50% MS in US. 2023E net sales USD 250m Retrospective study showed benefits vs. prednisone
Santhera	**vamorolone**	**Agamree**	"Dissociative" steroid	oral, daily	**Approved (USA) Oct-2023** **EU approval in Q4-23E**	FDA appr Oct 2023, >2 years, similar label to Emflaza Launch Q1-24E (US, EU9) US: slight discount to Emflaza
Exon-skipping & read-through agents - mutation-specific						
PTC Therapeutics	**ataluren**	**Translarna**	Nonsense-readthrough agent	Oral (3x/day)	Not filed/approved in the US **EU conditional approval 2014** Possible EU withdrawal (24E)	For 10-15% of DMD patients. EU price ~EUR 350k p.a. 2022 sales USD 289m CHMP advised against full approval
Sarepta	**eteplirsen**	**Exondys 51**	Exon-skipping (Exon 51) phosphorodiamidate morphino oligomer	Once-weekly IV infusion	**Accelerated aproval (USA) 2016** Confirmatory data in 2024E	For ~13% of DMD patients. First-in-class phosphorodiamidate morphino oligomer (PMO) 9M-23 revenues of USD 410m (US price USD 300k)
Biomarin	**drisapersen**	**Kyndrisa**	Exon-skipping (Exon 51)	Infusion	FDA CRL in 2016 EU application withdrawn	Annual costs USD 0.75-1.5m. (avg. ~USD 1.0m p.a.)
Sarepta	**golodirsen**	**Vyondis 53**	Exon-skipping (Exon 53)	Once-weekly IV	**Approved 2019 (US)**	For ~8% of DMD patients, ASP ~USD 1m/patient p.a.
Sarepta	**casimersen**	**Amondys 45**	Exon-skipping (Exon 45)	Once-weekly IV	**Approved 2021 (US)**	For ~8% of DMD patients, ASP ~USD 1m/patient p.a.
NS Pharma	**viltolarsen**	**Viltepso**	Exon-skipping (Exon 53)	Once-weekly IV	**Approved 2021 (US)**	For ~8% of DMD patients, ASP ~USD 1m/patient p.a.
Sarepta	**vesleteplirsen**	**SRP-5051**	Exon-skipping (Exon 51)	Injection	Phase II (Q4-23E read-out)	Next-generation Exon 51 skipping drug
Sarepta	**various**		Other exon targets: 44, 45, 50, 52, 53		Preclinical	
Entrada		**ENTR-601-44**	Exon 44 skipping (EEV-conjugated PMO)		Phase I	EEV thought to improve uptake of PMO by muscle cells
In-vivo gene correction / gene therapy - non-mutation specific						
Sarepta / Roche	**delandistrogene moxeparvovec**	**Elevidys**	rAAVrh74 delivery of MHCK7.micro-dystrophin gene	IV infusion (1x)	**US accelerated approval Jun-2023***, Confirmatory study missed 1°EP (Nov 2023)	Delivers micro-dystrophin-encoding gene *Amubulant boys (4-5 years). EU: not filed/approved USD 69m sales Q3. US price: USD 3.2m/net USD 2.4m
Pfizer	**fordadistrogene movaparvovec**	**PF-06939926**	rAAV9 delivery of mini-dystrophin	1 injection, 2 doses	Phase III was temporarily on hold. **Read-out H2-24E.**	In development in US & Japan, 2025E earliest launch AAV-based, delivers mini-dystrophyn gene
RegenxBio		**RGX-202**	NAV AAV8 vector		Phase I/II AFFINITY trial	n=12, includes boys aged 4-11 years
Astellas		**SGT-001**	rAAV9 delivery of micro-dystrophin	1 injection, 2 doses		Dropped the program (side effects)
Capricor Ther.	**Allogenic stem cell therapy**	**CAP-1002**	Allogeneic CDCs (cardiosphere-derived cells)		**Phase III** Approval potentially in 2025E	Cell-based, from donated heart muscle, to support heart function, focus on non-ambulatory patients
Sarepta	**genethon**	**GNT-0004**			Clinical development	
Other approaches/repurposing of drugs						
Santhera	idebenone		anti-oxidant		Terminated (Phase III)	To improve mitochondrial function
Fibrogen	pamrevlumab		anti-CTGF mAb (connective tissue growth factor)		**Phase III (first study failed)**	Non-ambulatory (>12yrs), with steroids, mutation-indep.
Italfarmaco	givinostat		Histone deacetylase inhibitor	oral	**Filed (PDUFA Dec 21, 2023)** **EU: filed, approval in H1-24E**	Ambulant patients (>6 years), independent of mutation, concomitant steroid use. Anti-fibrotic (mode of action)
Taiho/Otsuka	pizuglanstat	TAS-205	HPGDS inhibitor	oral	Phase III	Development in Japan
Edgewise		EDG-5006	Novel mode of action Targeting ATPase	small molecule	Phase II in DMD (incl. boys after previous gene therapy)	In development for DMD and in BMD. Not diease-modifying with and without steroid use. Phase III start in H2-24E
Catabasis	edasalonexent		NF-kB inhibitor		Failed in Phase III, stopped	
	metformin		increase pAMPK increase PGC1α			
	tamoxifen (repurposing)				Clinical development	To decrease muscle dystrophy pathology
	simvastatin (repurposing)				Preclinical	
	zidovudine (repurposing)		inhibits purinergic receptor (P2RX7) signaling		Preclinical	
CRISPR/Cas9 gene editing - mutation-specific						
Vertex	AAV9-based gene editing				Preclinical	
Cell transplants, Up-regulation of supporting molecules						
	myoblasts				Research/Preclinical	
	cardiospheres				Research/Preclinical	
	dystophin-expressing chimeric cells (DEC)				Research/Preclinical	
	utrophin				Research/Preclinical	
	SU9516	integrin-α7			Research/Preclinical	
	obestatin	integrin-α7			Research/Preclinical	
	sarcspan				Research/Preclinical	

Agamree: Market share gains from switching patients

Most therapies not approved in EU

First gene therapy in DMD; likely to remain on the market, despite mixed clinical data

Different approaches, complemetary to steroids

Source: Octavian

Commercial Strategy

North America – Catalyst Partnership

In North America, Santhera has out-licensed vamorolone to NASDAQ-listed Catalyst Pharmaceuticals

- **For the North American market, Santhera has established a commercial partnership.** In July 2023, Santhera and **US-based Catalyst Pharmaceuticals** entered into an exclusive license agreement for vamorolone, encompassing commercialization rights in the US, Canada, and Mexico. Catalyst is a Nasdaq-listed company (Ticker: CPRX) with a current market capitalization of ~CHF 1.5bn. The company currently has ~100 FTEs and is headquartered in Florida.

- **Catalyst focuses on therapies for rare neuromuscular and neurological diseases** and already markets two medicines in the US: (1) Firdapse for the rare neuromuscular condition LEMS (Lambert-Eaton myasthenic syndrome), and (2) Fycompa for Epilepsy. Total revenues are expected to be USD 390-395m in 2023E (+82-84% yoy), and non-GAAP income USD 195-205m. At the end of Q3-23, the company had USD 121m net cash.

Catalyst has not yet provided any peak sales expectations/guidance for Agamree

- **Agamree (vamorolone) will be launched in the US in Q1-24E.** Catalyst will leverage its neuromuscular franchise teams, which will only be slightly built up, with ~10 FTEs to be added including 4 US sales reps. The company is currently preparing for the launch and will reveal more details on the positioning and commercial strategy in the next months; also, to date, Catalyst has **not communicated its expectations for peak sales for Agamree**.

- Catalyst indicated in their Q3-23 results call that **Agamree will be priced at a slight discount to Emflaza** (referring to the wholesale acquisition price), likely to facilitate payor discussions.

A well-defined orphan disease market with focused DMD expert centers:

DMD	Centers	HCPs
U.S.	~90	~450
EU4+UK	~180	~750

Source: Santhera

- **Initially, the main target will be patients switching from Emflaza** (OctE: 40-50% market share in the steroid-treated DMD population in the US). Overall, we think that Catalyst, a specialized company with an established track record, is a good partner of choice. DMD is a focused market, with 90-100 centers treating patients in the US, and the DMD community (KOLs, patient advocacy groups, etc.) is already quite well acquainted with the product characteristics.

- Under the terms of the agreement, **Catalyst will pay Santhera up to USD 105m in potential future sales milestones** (the respective sales thresholds are not disclosed)**, and royalties of up to a low double-digit % of net sales**. This comes in addition to the upfront portion of USD 90m (USD 75m cash, USD 15m equity investment) and USD 10m to Santhera for US approval, received in Q4-23. Catalyst settled Santhera's obligation to pay Idorsia and ReveraGen the owed amount of USD 26m on approval. Further, Catalyst will assume all third-party licensing obligations on vamorolone sales in all indications in North America.

Sequence of Agamree launches in EU

Source: Santhera

First EU revenues should come from early access programs in the UK and France

In our model, we assume exclusivity in DMD until 2040E (US) and 2036E (EU)

Europe – Own Commercialization in Key Markets

- **Santhera is currently preparing for a staged market launch in Europe.** On October 13th, Santhera received a positive CHMP (Committee for Medicinal Products for Human Use Agency's) opinion in favor of the approval of vamorolone. Once approved, **Santhera plans to launch Agamree first in Germany, in Q1-24E**. UK will be the next launch, likely in early Q3-24E (NICE reimbursement is anticipated around May/June), followed by France. Italy and Spain are scheduled for early 25E.
- Santhera plans to market Agamree with a **direct sales force approach in core EU markets** (Germany, Spain, France, Italy, UK, Austria, Switzerland, and Benelux). The company expects this to be achievable with a **lean commercial organization** (up to 50 incremental FTEs in addition to today's set-up), given the relatively concentrated market structure with ~180 centers and ~750 physicians in EU4 and UK. The other EU markets will likely be tackled with distribution partners.

Early Access Program

- Santhera has **submitted a request for an early access program** for vamorolone for the treatment of DMD in **France** (AAP/autorisation d'accès précoce). If granted (likely in Q1 or Q2-24E), Santhera would already generate its first revenues in France, before market launch in H2-24E. Early access programs can serve as **first indicators of later commercial success**; however, as this will likely coincide with the German launch, a reasonable assessment is not feasible before mid-24E.

ROW – Partnership with Sperogenix for China

- In January 2022, Santhera out-licensed vamorolone rights in rare disease indications in **Greater China to local player Sperogenix**. Terms include a double-digit USD m upfront portion, a US-linked milestone (combined USD 20m), and double-digit royalties on sales. Regulatory filing will potentially happen in H1/Q2-24E, hence product approval could come by ~mid-25E, with subsequent launch by Sperogenix.
- In ROW territories, Santhera intends to out-license Agamree.

Intellectual Property, Orphan Drug Exclusivity

- Vamorolone was granted **orphan drug designation** from both the FDA and EMEA for the treatment of DMD, providing market exclusivity for **7 years (USA) and 10+2 years in EU** (incl. 2 years pediatric extension) following marketing approval. Hence, in the US this gives exclusivity until Q1-31E, and in the EU until 2036E.
- Vamorolone's composition of matter patent, which usually represents the strongest level of IP protection, has expired. Method of use IP was granted and, through extension, should provide exclusivity in **EU and other ROW markets until at least 2035E**. Further, a new IP on the polymorphic form (covering the formulation as a suspension) was filed in the **US, giving scope for IP protection until 2040E**.

Other Pipeline – Potential Upside

(not captured in our valuation)

Potential upside from the pipeline is not captured in our valuation

- **Lonodelestat**, licensed from Spexis, is an inhalable hNE (human neutrophil elastase) inhibitor. A Phase Ib trial in cystic fibrosis (CF) was completed, and the asset is Phase II-ready in CF and ARDS. However, given funding limitations and the focus on Agamree, development has been paused, and we understand that Santhera is open to partnerships. At this stage, considering the uncertain way forward for Spexis (SPEX SW, NR) and competitive dynamics in CF, we think it is **rather unlikely that development will be pursued.** In light of this and the early development phase, we don't include lonodelestat in our rNPV model.

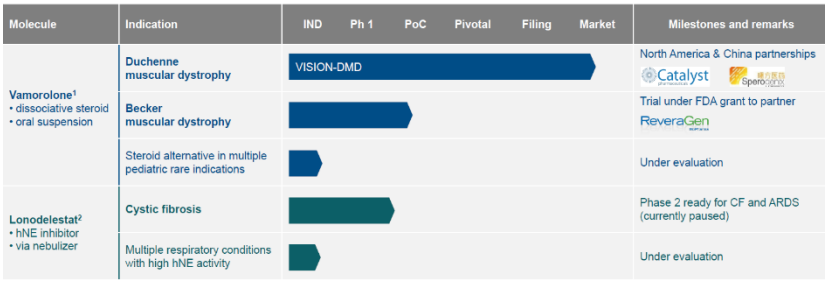
Vamorolone has potential in other therapeutic areas (update in H1-24E)

Therapeutic Area	Indication
Neurology	Becker Muscular Dystrophy*
	Myasthenia Gravis Ocular*
	Chronic Inflammatory Demyelinating Polyneuropathy
Pulmonology	Sarcoidosis*
	Idiopathic Interstitial Pneumonitis
Nephrology	Frequently Relapsing Nephrotic Syndrome*
	Membranous Nephropathy
Rheumatology	Dermatomyositis
	Juvenile Rheumatoid Arthritis
	Polymyalgia Rheumatica
Hematology	Genetic or Acquired Anemia
Hepatology	Autoimmune Hepatitis Type 2

* Indications with most advanced analyses

Source: Santhera

- Rather, we think that **Santhera will deploy funds towards additional indications for vamorolone.** As a steroid-class drug with a more benign side effect profile, vamorolone could have potential in a range of other indications next to DMD ("pipeline in a product").
- Hence, the company, together with its partner Catalyst, will jointly evaluate which programs to potentially pursue, with a **focus on pediatric rare indications**, and where prednisone is already the standard of cascaree. The development would take place under a cost-sharing agreement. Santhera believes that, as safety and efficacy were shown in a pediatric population, the FDA could, possibly, allow them to take it to Phase IIb pivotal studies in these other indications
- We anticipate hearing an **update in H1-24E on potential new indications** and respective development strategies and timelines; at this stage, we conservatively only include DMD in our valuation.



Source: Santhera company presentation

Financial Forecasts

We project revenues from Agamree commercial sales to strongly grow, with peak sales of CHF 132m in EU, and CHF 278m in US (booked by Catalyst)

- **Sales growth:** we estimate Santhera to achieve net sales (in Western EU) of CHF 8m (2024E), CHF 22m (2025E), and CHF 41m (2026E) driven by geographic expansion and increasing market share. We forecast peak sales of CHF 132m (2030E) in this region. In addition, we project revenues from out-licensing (which includes royalties from Agamree sales by North American partner Catalyst and milestone payments) to contribute ~CHF 13-15m p.a. in 2024-26E. In the long term, we estimate the royalty streams from Agamree US sales to approach ~CHF 32m p.a. (on peak sales of CHF 278m in 2030E). For more details on our sales assumptions, please refer to page 12.
- **Gross margin:** Vamorolone is a small molecule, with manufacturing outsourced to a CMO. We estimate COGS to amount to ~10%, allowing for high gross margins.

No guidance was provided for 2023E. We project gradually rising operating costs in 2024-26E driven by EU S&M investments

- **OPEX:** Santhera intends to have a direct commercial infrastructure in key EU markets. In other territories, it has already established partnerships (Catalyst/North America, and Sperogenix/China), and will work with distributors or partners. Santhera's launch strategy in Western EU involves the hiring of ~50 additional FTEs in total; commercial roll-out will start in Q1-24E in Germany and will be staged. Full coverage of the Western EU territories is anticipated by end-25E, driving S&M costs from an estimated CHF 10m (2023E) to CHF 26m (2026E); meanwhile, we expect G&A to remain rather stable at CHF 15-16m p.a. The level of R&D spending is difficult to forecast, as it depends on the plan for further development of vamorolone in new indications; we currently have it declining to CHF 12-15m p.a. (vs. CHF 31m in 2022, CHF 19m 2023E).

We estimate the operating loss to gradually diminish and see positive EBITDA in 2026E

- **Operating losses to diminish, EBITDA break-even in H2-26E:** We anticipate Santhera to report a profit in 2023E, thanks to the significant partnering income booked. The company has not issued a mid-term guidance; in our model, we assume that the operating loss will gradually diminish from an estimated EBITDA of CHF -22m (2024E) to CHF -12m (2025E), and estimate a positive EBITDA of CHF 3m in 2026E.
- **Balance sheet:** Thanks to the recent partnering-related cash inflows, Santhera was able to pay back a significant portion of its debt. Intangible assets of CHF 51m mostly relate to vamorolone.

We estimate a total funding gap of CHF 50m until profitability

- **Liquidity/Cash burn:** After the Catalyst transaction and the payback of exchangeable debt, Santhera had ~CHF 50m in cash (pro forma as of mid-23). Together with ~CHF 9m milestone income in H2-23E (related to US approval) and payments expected in 2024E (~CHF 9m from Chinese partner Sperogenix), **Santhera has a cash reach into Q1-25E as per company guidance (OctE: early Q1-25E)**. Note, that this does not include conversion or redemption of the '24 convertible bonds. In our model, we assume that the listed CHF 13.5m CB (conversion price of CHF 30), will be redeemed and refinanced. For the CHF 11.8m private CBs (conversion prices of CHF 5-10), we think it is more likely that they convert at maturity (underlying 1.677m shares). To reach break even, we estimate that **total cash injections of CHF 50m are required** (~CHF 36m for operational items, excluding the repayment of the '24 CB).
- **Returns to shareholders:** Given its development stage, Santhera is not paying any dividends and in our view, will not do this in the next years.

OCTAVIAN

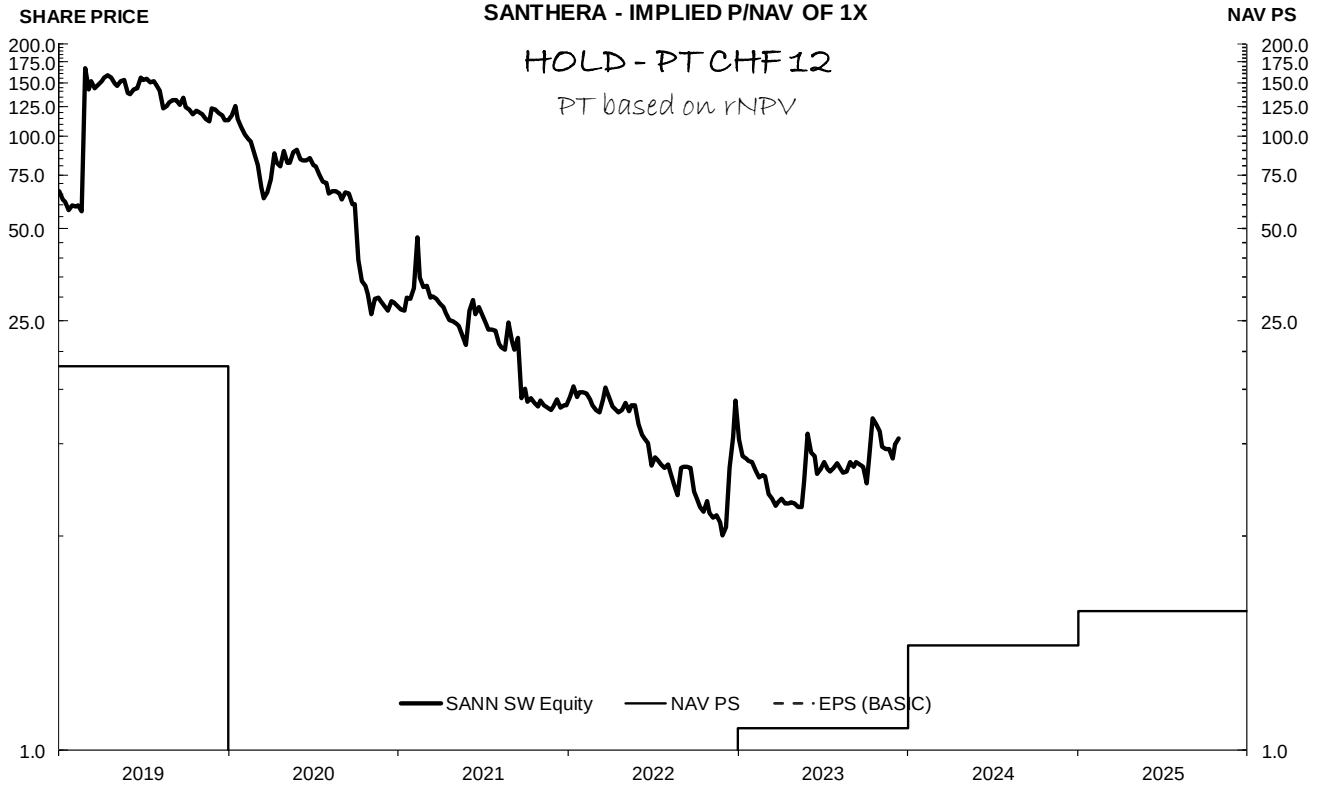
Financial Models

KEY FIGURES	CHF M		REG.
MARKET CAPITALISATION	109.9	PRICE ON DECEMBER 11, 2023 (CHF)	10.40
ENTERPRISE VALUE*	109.2	PRICE TARGET (CHF)	12
TOTAL REVENUES 2023E	73.9	RECOMMENDATION	HOLD
NET PROFIT/(LOSS) 2023E	20.9	DIVIDEND YIELD 2023E (%)	0.0%
EPS CAGR 2022-25E (%)	NM	PAR VALUE IN CHF	0.10
SHAREHOLDERS' EQUITY 2023E	14.1	NUMBER OF SHARES IN M**	10.564
NET LIQUID FUNDS (END 2022)	1.4	AVG. TRADING VOLUME ('000)	25
ACCOUNTING STANDARDS	IFRS	FREE FLOAT	79%
TICKER	SANN SW	MAJOR SHAREHOLDERS:	
NEXT EVENT: FY 2023 RESULTS	TBA	Catalyst Pharmaceuticals	11.2%
*as of end-23E		Idorsia	10.3%

RATIOS	2023E	2024E	2025E
P/E	NM	NA	NA
EV/S	1.5	4.5	2.8
P/NAV	8.8	4.7	3.7
EV/EBITDA	NM	NM	NM

PER SHARE DATA (CHF)	2019	2020	2021	2022	2023E	2024E	2025E
EPS (BASIC)	-17.30	-50.81	-16.25	-11.67	1.76	-1.95	-0.99
CHANGE IN %	*NM*	*194%*	*-68%*	*-28%*	*-115%*	*-210%*	*-49%*
EPS (DILUTED)	-17.30	-50.81	-16.25	-11.67	1.76	-1.93	-0.99
CHANGE IN %	*NM*	*194%*	*-68%*	*-28%*	*-115%*	*-210%*	*-49%*
DIVIDEND	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PAYOUT IN %	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
NET ASSET VALUE	17.75	-4.44	0.38	-7.05	1.18	2.20	2.83
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
NO. OF SHARES AT YEAR-END***	1.1	1.9	5.5	7.5	12.6	17.0	19.8
AVERAGE NO. OF SHARES	1.1	1.3	3.4	6.1	11.9	14.8	18.4

SOURCE: OCTAVIAN ***Reverse share split (ratio 10:1) in July 2023. **Excluding treasury shares (1.995m)



OCTAVIAN

Raxone (LHON) fully divested to Chiesi as of July 2023 Agamree launch Q1-24E: Direct sales (EU countries); royalties from US

INCOME STATEMENT (CHF M)	2019	2020	2021	H1	H2	2022	H1	H2E	2023E	2024E	2025E	2026E
NET SALES (AGAMREE IN EU)	27.9	11.3	-5.0	-5.9	0.3	-5.6	1.0	0.0	1.0	8.4	22.2	40.7
- CHANGE IN %	*-12%*	*-60%*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*163%*	*83%*
REVENUES OUT-LICENSING	46.4	1.6	1.1	11.2	0.0	11.2	1.9	70.0	71.9	13.2	14.4	15.0
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*10%*	*4%*
Net sales to Chiesi	1.1	2.2	2.2	0.9	0.9	1.9	1.0	0.0	1.0			
TOTAL REVENUES	**75.4**	**15.0**	**-1.6**	**6.3**	**1.2**	**7.5**	**3.9**	**70.0**	**73.9**	**21.6**	**36.6**	**55.7**
- CHANGE IN %	*138%*	*-80%*	*-111%*	*64%*	*-123%*	*-569%*	*-37%*	*NM*	*889%*	*-71%*	*70%*	*52%*
GROSS PROFIT	**69.9**	**5.3**	**-5.0**	**4.5**	**-0.3**	**4.1**	**2.0**	**70.0**	**72.0**	**20.6**	**34.2**	**51.7**
- IN % OF REVENUES	***93%***	***35%***	***314%***	***71%***	***-26%***	***55%***	***51%***	***NM***	***97%***	***95%***	***93%***	***93%***
R&D	41.2	34.2	29.7	16.9	13.7	30.5	9.7	9.3	19.0	15.0	12.0	12.0
- CHANGE IN %	*8%*	*-17%*	*-13%*	*73%*	*-32%*	*3%*	*-42%*	*-32%*	*-38%*	*-21%*	*-20%*	*0%*
- IN % OF REVENUES	*55%*	*228%*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*69%*	*33%*	*22%*
MARKETING AND SALES	20.1	11.5	9.3	5.9	4.9	10.9	4.3	5.8	10.0	17.0	23.5	26.0
- CHANGE IN %	*-19%*	*-43%*	*-19%*	*NM*	*NM*	*16%*	*-28%*	*17%*	*-7%*	*70%*	*38%*	*11%*
- IN % OF REVENUES	*27%*	*76%*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*79%*	*64%*	*47%*
GENERAL & ADMINISTRATIVE	19.2	12.4	12.7	7.1	7.4	14.6	8.4	8.6	17.0	15.0	15.5	16.0
- CHANGE IN %	*25%*	*-35%*	*2%*	*2%*	*30%*	*14%*	*17%*	*16%*	*16%*	*-12%*	*3%*	*3%*
TOTAL SG&A	**39.3**	**23.9**	**22.1**	**13.1**	**12.4**	**25.4**	**12.6**	**14.4**	**27.0**	**32.0**	**39.0**	**42.0**
NET OTHER EXPENSES	-0.2	-0.5	-0.2	0.0	-0.1	-0.1	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL OPERATING COST	60.4	58.3	51.9	30.0	26.1	56.1	18.1	17.9	46.0	47.0	51.0	54.0
- CHANGE IN %		*-3%*	*-11%*	*79%*	*2%*	*8%*	*-40%*	*-32%*	*-18%*	*2%*	*9%*	*6%*
EBITDA	**-5.7**	**-45.9**	**-53.2**	**-23.7**	**-18.4**	**-42.1**	**-18.5**	**48.3**	**29.8**	**-22.2**	**-12.0**	**3.3**
DEPRECIATION	1.7	4.0	0.6	0.3	0.3	0.6	0.3	0.3	0.6	0.8	1.0	1.5
AMORTIZATION	3.1	3.2	3.1	1.5	7.7	9.3	1.5	1.6	3.1	3.4	3.8	4.2
EBIT	**-10.4**	**-53.1**	**-56.9**	**-25.5**	**-26.4**	**-52.0**	**-20.3**	**46.4**	**26.1**	**-26.4**	**-16.8**	**-2.3**
NET FINANCIAL RESULT	-8.0	-14.4	2.2	-3.6	-15.0	-18.6	-3.1	-2.0	-5.1	-2.4	-1.5	-1.5
INCOME BEFORE TAXES	**-18.4**	**-67.5**	**-54.7**	**-29.1**	**-41.5**	**-70.6**	**-23.4**	**44.4**	**20.9**	**-28.8**	**-18.3**	**-3.8**
TAX	0.6	0.2	0.8	0.6	-0.1	0.5	-0.1	0.1	0.0	0.0	0.0	0.0
- TAX RATE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
NET PROFIT/(LOSS)	**-19.0**	**-67.7**	**-55.5**	**-29.7**	**-41.4**	**-71.1**	**-23.3**	**44.3**	**20.9**	**-28.8**	**-18.3**	**-3.8**
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
- IN % OF SALES	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*

BALANCE SHEET (CHF M)	2019	2020	2021	H1		2022	H1		2023E	2024E	2025E	2026E
INTANGIBLE ASSETS	58.5	67.7	64.6	63.1		59.2	51.1		43.1	40.7	56.4	54.2
TOTAL NON-CURRENT ASSETS	**65.8**	**71.0**	**66.5**	**65.2**		**60.7**	**52.3**		**44.3**	**42.1**	**58.3**	**56.6**
CASH & CASH EQUIVALENTS	32.9	12.4	21.2	12.7		1.4	1.7		28.8	14.4	8.3	9.4
TOTAL CURRENT ASSETS	**49.3**	**17.7**	**24.6**	**14.6**		**3.1**	**4.1**		**32.7**	**21.6**	**21.1**	**30.0**
TOTAL ASSETS	**115.1**	**88.7**	**91.1**	**79.8**		**63.7**	**63.1**		**77.0**	**63.6**	**79.4**	**86.6**
NET LIQUID FUNDS	**-23.9**	**-56.2**	**-30.4**	**-35.4**		**-59.0**	**-52.7**		**2.4**	**14.4**	**8.3**	**9.4**
CONVERTIBLE BONDS ('24)	56.2	57.9	25.8	24.9		21.1	19.2		19.2	0.0	0.0	0.0
DERIVATIVE FINANCIAL INSTR.	0.6	0.0	3.7	2.0		4.3	4.8		4.8	0.0	0.0	0.0
WARRANT FINANCIAL INSTR.	0.0	0.0	4.7	2.3		5.2	2.4		2.4	0.0	0.0	0.0
TOTAL NON-CURRENT LIAB.	**69.8**	**66.0**	**57.0**	**55.1**		**58.0**	**28.5**		**33.5**	**7.0**	**7.0**	**7.0**
TOTAL CURRENT LIABILITIES	**24.0**	**29.1**	**32.8**	**38.6**		**49.4**	**52.6**		**29.4**	**33.4**	**42.5**	**53.5**
LIABILITY ASSOCIATED WITH ASSETS HELD FOR SALE (Raxone)							24.8		0.0	0.0	0.0	0.0
SHAREHOLDERS' EQUITY	**21.2**	**-6.4**	**1.3**	**-13.8**		**-43.7**	**-42.8**		**14.1**	**23.2**	**29.9**	**26.0**
- CHANGE IN %	*-24%*	*-130%*	*-121%*			*NM*	*NM*		*NM*	*64%*	*29%*	*-13%*
- RETURN ON EQUITY	*NM*	*NM*	*NM*	*NM*		*NM*	*NM*		*NM*	*NM*	*NM*	*-15%*
TOTAL EQUITY & LIABILITIES	**115.1**	**88.7**	**91.1**	**79.8**		**63.7**	**63.1**		**77.0**	**63.6**	**79.4**	**86.6**
NO. OF FTEs	177	149	67	67		66	67		67	85	100	115

CASH FLOW (CHF M)	2019	2020	2021	H1	H2	2022	H1	H2E	2023E	2024E	2025E	2026E
NET PROFIT / (LOSS) BEFORE TAXES	-19.0	-67.5	-54.7	-29.1	-41.5	-70.6	-23.3	44.3	20.9	-28.8	-18.3	-3.8
+ DEPRECIATION & AMORTIZATION	4.8	7.1	3.7	1.8	8.0	9.9	1.8	1.9	3.7	4.2	4.8	5.7
+ SHARE-BASED COMPENSATION	6.3	3.0	2.8	1.5	4.0	5.5	1.9	2.1	4.0	5.0	6.0	7.0
+ NET CHANGE IN WORKING CAPITAL	-3.6	3.2	1.8	2.6	-1.2	1.4	3.7	-2.2	1.5	-4.2	-2.6	-3.7
+ CASH FROM PARTNERING (not included in revenue)							0.0	5.0	5.0	0.0	0.0	0.0
- CASH OUT FOR MILESTONE PAYMENTS							0.0	0.0	0.0	0.0	-18.0	0.0
+ OTHER ITEMS	14.2	10.5	9.1	11.4	12.7	24.1	0.6	-0.6	0.0	0.0	0.0	0.0
OPERATING CASH FLOW	**2.6**	**-43.5**	**-37.4**	**-12.0**	**-17.9**	**-29.8**	**-15.3**	**50.4**	**35.2**	**-23.8**	**-28.1**	**5.1**
- CAPITAL EXPENDITURE (net)	-0.2	0.0	0.0	0.0	-4.0	-4.0	0.0	0.5	0.5	2.0	3.0	4.0
+ CHANGE LT FIN. ASSETS/RESTR. CASH	3.0	1.6	0.0	0.0	0.1	0.1	5.7	-5.7	0.0	0.0	0.0	0.0
FREE CASH FLOW	**5.8**	**-41.9**	**-37.3**	**-12.0**	**-13.8**	**-25.8**	**-9.6**	**44.3**	**34.7**	**-25.8**	**-31.1**	**1.1**
+ PROCEEDS/(PURCHASE) TREASURY SHARES	0.0	0.0	0.0	0.0	0.5	0.5	0.6	-0.6	0.0	0.0	0.0	0.0
+ PROCEEDS CAPITAL INCREASES	7.1	0.0	20.3	0.0	0.0	0.0	2.3	12.6	14.9	25.0	25.0	0.0
+ PROCEEDS EXERCISE OF EQUITY RIGHTS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
+ PROCEEDS EXCHANGEABLE NOTES	0.0	0.0	22.0	18.0	15.0	33.0	7.5	0.0	7.5	0.0	0.0	0.0
- REPAYMENT OF EXCHANGEABLE NOTES	0.0	0.0	-3.5	0.0	0.0	0.0	0.0	-29.8	-29.8	0.0	0.0	0.0
+ PROCEEDS CONVERTIBLE NOTES	0.0	24.6	13.8	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0
- REPAYMENT/REPURCH. CONV. BONDS	0.0	0.0	0.0	-13.9	-4.5	-18.4	0.0	0.0	0.0	-13.5	0.0	0.0
+ OTHER	-3.1	-1.5	-6.5	-0.6	-0.5	-1.1	-0.7	0.7	0.0	0.0	0.0	0.0
CHANGE IN LIQUID FUNDS	**9.8**	**-18.9**	**8.8**	**-8.5**	**-3.4**	**-11.9**	**0.3**	**27.1**	**27.4**	**-14.4**	**-6.1**	**1.1**

USD 75m cash upfront portion from Catalyst transaction, plus USD 10m US approval milestone (OctE: thereof CHF 5m booked as deferred revenue)

Includes milestone China

R&D depending on planned next indications for vamorolone (tba)

Staged EU launch, preparation costs to start in Q4-23E, further ramping up in 2024E (sequential market launches); at peak level end-25E

~CHF 50m cash after all transactions in mid-23

OctE: Cash reach into early Q1-25E (company guidance Q1-25E) - excluding any debt payback in 2024E

Milestone payment to Idorsia, Reveragen (USD 20m)

USD 15m equity investment by Catalyst (purchase of 1.4m treasury shares)

Exchangeable debt repaid after Catalyst deal

SOURCE: OCTAVIAN

We assume repayment of the CHF 13.58m public bond (Aug-24E, conversion price CHF 30.03), and conversion of CHF 13m private CB (conversion price CHF 5-10) --> 1.677m shares underlying

OctE: CHF 50m total cash injections required to bridge until profitability

OCTAVIAN

AGAMREE (VAMOROLONE) SALES MODEL

Indication

Duchenne Muscular Dystrophy (alternative to glucocorticoids)
First-in-class anti-inflammatory NFkB modulator ("dissociative steroid"), oral suspension
Modifies downstream activity of receptor, avoiding hormonal transactivation, anti-inflammatory action
Better tolerability profile than glucocorticoids - ambition to replace as SOC (for broad segment of DMD patients)
FDA label: corticosteroid for DMD patients 2 years and older, recommended dose is 6mg/kg/day, max 300mg (for >50kg)
EU label (expected): for DMD patients >4 years, more benign side effect profile

US: pricing at a small discount to Emflaza
EU: May/Jun 24E reimbursement decision in UK, mid-24E price negotiations in Germany

Expected timelines

Status: FDA approved (Oct 23, 2023), approval based on pivotal global Phase IIb trial, VISION-DMD (121 patients, 4 to >7 ys)
EU approval pending (positive CHMP opinion on Oct 12, 2023), UK MHRA decision in Q4-23E Rare pediatric disease designation
US: launch Q1-24E | **EU: launch Q1-24E**

Commercialisation

EU5, CH, A, Benelux: Santhera; others tbd. Company estimates ~180 centers and ~750 specialists in EU5
US/Canada/Mexico: Catalyst Pharmaceuticals China: Sperogenix

Net price at launch (US) - Oct E 85'000 USD (average per patient)
Net price at launch (EU) - Oct E 30'000 EUR (average per patient)

Exclusivity

Orphan drug protection (7 years US, 10+2 years EU), IP protection until 2035E (EU) and 2040E (US)

UNITED STATES (IN CHF M)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Estimated Prevalence of DMD (1:3'500)*	12'228	12'313	12'400	12'486	12'574	12'662	12'750	12'840	12'930	13'020	13'111	13'203
Thereof ambulatory (young boys)	50%											
No. of ambulant boys	6'114	6'157	6'200	6'243	6'287	6'331	6'375	6'420	6'465	6'510	6'556	6'602
Thereof % using steroids (SOC)	95%	95%	95%	95%	95%	95%	95%	94%	93%	92%	91%	90%
Ambulant patients using steroids	5'808	5'849	5'890	5'931	5'973	6'014	6'056	6'035	6'012	5'989	5'966	5'941
% penetration rate Agamree	4%	12%	19%	26%	33%	40%	45%	45%	45%	45%	45%	45%
No. of patients treated	232	702	1'119	1'542	1'971	2'406	2'725	2'716	2'706	2'695	2'685	2'674
Potential from young non-GC users (5%)	306	308	310	312	314	317	319	385	453	521	590	660
% penetration rate Agamree	2%	5%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%
No. of patients treated	6	15	31	47	63	79	96	116	136	156	177	198
Thereof non-ambulatory (older boys & men)	50%											
No. of non-ambulatory patients	6'114	6'157	6'200	6'243	6'287	6'331	6'375	6'420	6'465	6'510	6'556	6'602
Thereof % using steroids (SOC)	45%	45%	45%	45%	45%	45%	45%	44%	43%	42%	41%	40%
Non-ambulant patients using steroids	2'751	2'771	2'790	2'809	2'829	2'849	2'869	2'825	2'780	2'734	2'688	2'641
% penetration rate Agamree	4%	12%	19%	26%	33%	40%	45%	45%	45%	45%	45%	45%
No. of patients treated	110	332	530	730	934	1'140	1'291	1'271	1'251	1'230	1'210	1'188
Total concomitant steroid users	8'566	8'635	8'711	8'787	8'865	8'942	9'021	8'975	8'928	8'880	8'830	8'780
- In % of all DMD patients	*70%*	*70%*	*70%*	*70%*	*71%*	*71%*	*71%*	*70%*	*69%*	*68%*	*67%*	*67%*
Total no. of patients treated with Agamree	348	1'050	1'680	2'319	2'967	3'624	4'112	4'102	4'092	4'082	4'071	4'060
In % of total steroid users	4%	12%	19%	26%	33%	41%	46%	46%	46%	46%	46%	46%
In % of total DMD patients	3%	9%	14%	19%	24%	29%	32%	32%	32%	31%	31%	31%
- Patient adherence (compliance)	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
No. of annual Agamree prescriptions	296	892	1'428	1'971	2'522	3'081	3'495	3'487	3'478	3'470	3'460	3'451
ASP (list price) per year/patient (USD '000)	121	123	124	125	126	128	129	129	129	129	129	129
- Gross to net adjustment	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Net Price per year/patient to Catalyst (USD)	85'000	85'850	86'709	87'576	88'451	89'336	90'229	90'229	90'229	90'229	90'229	90'229
Net Price per year/patient to Catalyst (CHF)	74'800	75'548	76'303	77'067	77'837	78'616	79'402	79'402	79'402	79'402	79'402	79'402
USD/CHF = 0.88												
US SALES (CHF M) booked by Catalyst	**22**	**67**	**109**	**152**	**196**	**242**	**278**	**277**	**276**	**275**	**275**	**274**
- Change in %	***NM***	***204%***	***62%***	***39%***	***29%***	***23%***	***15%***	***0%***	***0%***	***0%***	***0%***	***0%***

Steroid users

We model a slight decline in steroid use after 2023OE

We estimate that almost half of US steroid users will use Agamree, and ~1/3 of all DMD patients at peak

WESTERN EUROPE (IN CHF M)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Estimated Prevalence of DMD (1:3'500)*	12'084	12'169	12'254	12'340	12'426	12'513	12'600	12'689	12'778	12'867	12'957	13'048
Thereof ambulatory (young boys)	50%											
No. of ambulant boys	6'042	6'084	6'127	6'170	6'213	6'256	6'300	6'344	6'389	6'433	6'479	6'524
Thereof % using steroids (SOC)	95%	95%	95%	95%	95%	95%	95%	94%	93%	92%	91%	90%
Ambulant patients using steroids	5'740	5'780	5'821	5'861	5'902	5'944	5'985	5'964	5'942	5'919	5'895	5'871
% penetration rate Agamree	4%	10%	17%	27%	37%	46%	50%	50%	50%	50%	50%	50%
No. of patients treated	230	549	960	1'553	2'184	2'734	2'993	2'982	2'971	2'959	2'948	2'936
Potential from young non-GC users (5%)	302	304	306	308	311	313	315	381	447	515	583	652
% penetration rate Agamree	2%	5%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%
No. of patients treated	6	15	31	46	62	78	95	114	134	154	175	196
Thereof non-ambulatory (asolescents)	50%											
No. of non-ambulatory DMD patients	6'042	6'084	6'127	6'170	6'213	6'256	6'300	6'344	6'389	6'433	6'479	6'524
Thereof % using steroids (SOC)	45%	45%	45%	45%	45%	45%	45%	44%	43%	42%	41%	40%
Non-ambulant patients using steroids	2'719	2'738	2'757	2'776	2'796	2'815	2'835	2'792	2'747	2'702	2'656	2'610
% penetration rate Agamree	4%	10%	17%	27%	37%	46%	50%	50%	50%	50%	50%	50%
No. of patients treated	109	260	455	736	1'034	1'295	1'418	1'396	1'374	1'351	1'328	1'305
Total concomitant steroid users	8'465	8'533	8'608	8'684	8'760	8'837	8'915	8'869	8'823	8'775	8'727	8'677
- In % of all DMD patients	*70%*	*70%*	*70%*	*70%*	*71%*	*71%*	*71%*	*70%*	*69%*	*68%*	*67%*	*67%*
Total no. of patients treated with Agamree	344	824	1'446	2'335	3'280	4'107	4'505	4'492	4'479	4'465	4'451	4'436
In % of total steroid users	4%	10%	17%	27%	37%	46%	51%	51%	51%	51%	51%	51%
In % of total DMD patients	3%	7%	12%	19%	26%	33%	36%	35%	35%	35%	34%	34%
- Patient adherence (compliance)	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
No. of annual Agamree prescriptions	293	701	1'229	1'985	2'788	3'491	3'829	3'818	3'807	3'795	3'783	3'771
Net Price per year/patient to Santhera (EUR)	30'000	30'000	30'000	30'000	30'000	30'000	30'000	30'000	30'000	30'000	30'000	30'000
Net Price per year/patient to Santhera (CHF)	28'800	28'800	28'800	28'800	28'800	28'800	28'800	28'800	28'800	28'800	28'800	28'800
EUR/CHF = 0.96												
TOTAL DIRECT SALES (CHF M)	**8**	**20**	**35**	**57**	**80**	**101**	**110**	**110**	**110**	**109**	**109**	**109**
SALES OTHER EU MARKETS (25% of EU5)	**0**	**2**	**5**	**11**	**16**	**20**	**22**	**22**	**22**	**22**	**22**	**22**
EU NET SALES (CHF M) - booked by Santhera	**8**	**22**	**41**	**69**	**96**	**121**	**132**	**132**	**132**	**131**	**131**	**130**
- Change in %	***NM***	***163%***	***83%***	***69%***	***40%***	***25%***	***10%***	***0%***	***0%***	***0%***	***0%***	***0%***

Steroid users

We model a slight decline in steroid use after 2023OE

We conservatively estimate the average reimbused net price to be at EUR 30k/patient (if EUR 32-35k --> ~5-15% upside potential)

*Prevalence of 1:3'500 to 1:5'000 in boys aged 5-24 years

We estimate CHF 132m peak sales in EU markets (OctE: ~50% of all steroid users at peak, some caution on the pricing), vs Santhera expecting sales of >CHF 150m in EU (direct markets)

ROW/JP/CHINA NET SALES (CHF M)*	**0**	**3**	**10**	**16**	**23**	**29**	**36**	**42**	**42**	**42**	**42**	**42**
- Change in %	***NM***	***204%***	***62%***	***39%***	***29%***	***23%***	***15%***	***0%***	***0%***	***0%***	***0%***	***0%***

*0.15 multiplier of US sales, launch 2024E. Likely to be partnered/outlicensed. China: outlicensed to Simcere.

Global peak sales of ~CHF 450m in DMD

GLOBAL AGAMREE NET SALES (CHF M)	**31**	**93**	**160**	**237**	**315**	**392**	**446**	**450**	**449**	**448**	**447**	**446**
	NM	***204%***	***72%***	***48%***	***33%***	***24%***	***14%***	***1%***	***0%***	***0%***	***0%***	***0%***

SOURCE: OCTAVIAN ESTIMATES

OCTAVIAN

VAMOROLONE USA (IN DMD)

Approved on October 26, 2023. US launch in Q1-24E — LOE (IP): 2040E

Partnered with Catalyst Pharmaceuticals (USA/Canada/Mexico) — Orphan drug exclusivity: 7 yrs

Deal terms: USD 90m upfront (USD 75m in cash, USD 15m in equity). Catalyst assumes royalty obligations to Reveragen & IDIA in NA. USD 10m milestone (US approval), plus USD 26m to be paid to 3rd parties. In additon, potential sales milestones up to USD 105m and up to low-teens % royalties on net sales (OctE: 9-12%)

Emflaza (PTC): Revenues of USD 255m (2023E), USD 218m (2022)

CHF M	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	
SALES (booked by Catalyst)	**0.0**	**22.2**	**67.4**	**109.0**	**151.9**	**196.3**	**242.2**	**277.5**	**276.9**	**276.2**	**275.5**	**274.8**	**274.0**	**274.0**	**274.0**	**274.0**	
- GROWTH	*NA*	*NM*	*204%*	*62%*	*39%*	*29%*	*23%*	*15%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	
CASH FROM CATALYST (UPFRONT, NET)	**78.6**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
US APPROVAL MILESTONE INCOME (NET)	**9.0**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
INCOME FROM SALES MILESTONES (OctE), NET					4.5		4.5	18.0			18.0						
ROYALTY INCOME (OctE: 9-12%)	**0.0**	**2.0**	**6.7**	**10.9**	**16.0**	**20.6**	**26.6**	**31.9**	**31.8**	**31.8**	**31.7**	**31.6**	**31.5**	**31.5**	**31.5**	**31.5**	
- Royalty rate	*NM*	*9%*	*10%*	*10%*	*11%*	*11%*	*11%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	
ALLOCATED SG&A COSTS	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	
EBIT	**86.6**	**1.0**	**5.7**	**9.9**	**19.5**	**19.6**	**30.1**	**48.9**	**30.8**	**30.8**	**48.7**	**30.6**	**30.5**	**30.5**	**30.5**	**30.5**	
- AS % OF NET SALES (booked by partner)	*NM*	*4%*	*9%*	*9%*	*13%*	*10%*	*12%*	*18%*	*11%*	*11%*	*18%*	*11%*	*11%*	*11%*	*11%*	*11%*	
TAXES	15.6	0.2	1.0	1.8	3.5	3.5	5.4	8.8	5.6	5.5	8.8	5.5	5.5	5.5	5.5	5.5	
- TAX RATE	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	
CASH FLOW	**71.0**	**0.8**	**4.7**	**8.1**	**16.0**	**16.1**	**24.7**	**40.1**	**25.3**	**25.2**	**39.9**	**25.1**	**25.0**	**25.0**	**25.0**	**25.0**	
- CHANGE IN %	*NM*	*NM*	*NM*	*72%*	*97%*	*1%*	*54%*	*62%*	*-37%*	*0%*	*58%*	*-37%*	*0%*	*0%*	*0%*	*0%*	
WACC (%)																**15.0**	
PERPETUAL GROWTH																	
NUMBER OF YEARS	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	
DISCOUNT FACTOR	1.00	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25	0.21	0.19	0.16	0.14	0.12	
DISC. CASH FLOW	**71.0**	**0.7**	**3.6**	**5.3**	**9.1**	**8.0**	**10.7**	**15.1**	**8.3**	**7.2**	**9.9**	**5.4**	**4.7**	**4.1**	**3.5**	**3.1**	**NPV**
PROBABILITY ADJ.	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	**CHF M**
NPV PROBABILITY-ADJUSTED	**71.0**	**0.7**	**3.6**	**5.3**	**9.1**	**8.0**	**10.7**	**15.1**	**8.3**	**7.2**	**9.9**	**5.4**	**4.7**	**4.1**	**3.5**	**3.1**	
TOTAL DISCOUNTED CASH FLOWS																	170
																	170

VAMOROLONE EU (IN DMD)

SANN targets in 5 years >EUR 150m in sales (EU5) — IP: 2035E

EU ~180 DMD centers in EU5, ~750 HCPs - small teams sufficient ot cover the market — Orphan drug excl.: 10+2 years

~50 additional FTEs needed for EU commercialization — 2036E

USD 20m milestone payment to IDIA & Reveragen for EU (early 25E) - once they have commercial revenue from 3 out of 5 countries (DE, UK; F)

CHF M	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	
SALES	**0.0**	**8.4**	**22.2**	**40.7**	**68.6**	**96.4**	**120.7**	**132.3**	**132.0**	**131.6**	**131.2**	**130.7**	**130.3**	**104.3**	**52.1**	**26.1**	
- GROWTH		*NA*	*NM*	*83%*	*69%*	*40%*	*25%*	*10%*	*0%*	*0%*	*0%*	*0%*	*0%*	*-20%*	*-50%*	*-50%*	
COGS (~10%)	0.0	1.0	2.4	4.1	6.9	9.6	12.1	13.2	13.2	13.2	13.1	13.1	13.0	10.4	6.3	3.1	
MILESTONE PAYMENTS TO REVERAGEN & IDORSI	0.0	0.0	**18.0**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
ROYALTIES TO REVERAGEN (5-8%) & IDORSIA (2.5%)	0.0	0.5	1.4	3.1	5.8	8.2	11.5	12.6	12.5	12.5	12.5	12.4	12.4	9.9	3.4	1.6	
- total in % of sales		*6.0%*	*6.5%*	*7.5%*	*8.5%*	*8.5%*	*9.5%*	*9.5%*	*9.5%*	*9.5%*	*9.5%*	*9.5%*	*9.5%*	*9.5%*	*6.5%*	*6.0%*	
R&D	5.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
SG&A	11.0	20.0	27.0	30.0	31.0	32.0	33.0	34.0	35.0	36.0	37.0	38.0	39.0	30.0	17.0	8.5	
EBIT	**-16.0**	**-16.1**	**-26.7**	**3.6**	**24.9**	**46.5**	**64.1**	**72.5**	**71.2**	**69.9**	**68.6**	**67.2**	**65.9**	**53.9**	**25.5**	**12.9**	
- EBIT MARGIN IN %	*NM*	*NM*	*-120%*	*9%*	*36%*	*48%*	*53%*	*55%*	*54%*	*53%*	*52%*	*51%*	*51%*	*52%*	*49%*	*49%*	
TAXES	-2.9	-2.9	-4.8	0.6	4.5	8.4	11.5	13.1	12.8	12.6	12.3	12.1	11.9	9.7	4.6	2.3	
- TAX RATE	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	
CASH FLOW	**-13.1**	**-13.2**	**-21.9**	**2.9**	**20.4**	**38.2**	**52.6**	**59.5**	**58.4**	**57.3**	**56.2**	**55.1**	**54.0**	**44.2**	**20.9**	**10.6**	
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*595%*	*87%*	*38%*	*13%*	*-2%*	*-2%*	*-2%*	*-2%*	*-2%*	*-18%*	*-53%*	*-49%*	
WACC (%)																**15.0**	
PERPETUAL GROWTH																	
NUMBER OF YEARS	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	
DISCOUNT FACTOR	1.00	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25	0.21	0.19	0.16	0.14	0.12	
DISC. CASH FLOW	**-13.1**	**-11.5**	**-16.5**	**1.9**	**11.7**	**19.0**	**22.7**	**22.4**	**19.1**	**16.3**	**13.9**	**11.9**	**10.1**	**7.2**	**3.0**	**1.3**	**NPV**
																	CHF M
TOTAL DISCOUNTED CASH FLOWS	100%																119
NPV AT 90% PROBABILITY	**90%**																**107**

SG&A: Company will go direct with a small sales force in EU4 + UK, Austria, Benelux and Switzerland, and use distributors in other EU markets

VAMOROLONE ROW (IN DMD)

China: partnered (Sperogenix). Filing in Q2-24E

OctE: 6m USD in 2024E (linked to US approval), USD 4m for China filing, USD 5m for approval (2025E)

Other territories: To be partnered/outlicensed

CHF M	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	
SALES (via partner)	0.0	0.0	3.3	10.1	16.3	22.8	29.4	36.3	41.6	41.5	41.5	41.5	41.5	41.5	41.5	41.5	
- GROWTH	*NM*	*NM*	*NM*	*204%*	*62%*	*39%*	*29%*	*23%*	*15%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	
CHINA MILESTONE INCOME	**0.0**	**9.0**	**4.5**														
ROYALTIES (OctE: 15%)	**0.0**	**0.0**	**0.5**	**1.5**	**2.5**	**3.4**	**4.4**	**5.4**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	
EBIT	**0.0**	**9.0**	**5.0**	**1.5**	**2.5**	**3.4**	**4.4**	**5.4**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	**6.2**	
- AS % OF SALES	*NM*	*NM*	*150%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	
TAXES	0.0	1.6	0.9	0.3	0.4	0.6	0.8	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	
- TAX RATE	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	
CASH FLOW	**0.0**	**7.4**	**4.1**	**1.2**	**2.0**	**2.8**	**3.6**	**4.5**	**5.1**	**5.1**	**5.1**	**5.1**	**5.1**	**5.1**	**5.1**	**5.1**	
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*62%*	*39%*	*29%*	*23%*	*15%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	
WACC (%)																**15.0**	
PERPETUAL GROWTH																	
NUMBER OF YEARS	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	
DISCOUNT FACTOR	1.00	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25	0.21	0.19	0.16	0.14	0.12	
DISC. CASH FLOW	**0.0**	**6.4**	**3.1**	**0.8**	**1.1**	**1.4**	**1.6**	**1.7**	**1.7**	**1.5**	**1.3**	**1.1**	**1.0**	**0.8**	**0.7**	**0.6**	**NPV**
																	CHF M
TOTAL DISCOUNTED CASH FLOWS	100%																25
NPV AT 80% PROBABILITY	**80%**																**20**

OTHER INCOME/SPEND

Vamorolone in other indications - potential for development in other indications (to be discussed with Catalyst)
Clinical trials unlikely to start before end-24E/2025E (cost sharing with Catalyst)
Inhaled Lonodelestat in Cystic Fibrosis: licensed from Polyphor (Q1-21 completed Phase) - project is on HOLD
Gene therapy (congenital muscular dystrophy), preclinical

CHF M	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	
OTHER INCOME	3.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
R&D NOT ALLOCATED ABOVE (PROBABILITY ADJ.)	14.0	12.0	12.0	12.0	8.0	6.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	
SG&A NOT ALLOCATED ABOVE (PROB. ADJ.)	15.0	11.0	11.0	11.0	9.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	
EBIT	**-25.1**	**-23.0**	**-23.0**	**-23.0**	**-17.0**	**-13.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	**-10.0**	
TAXES	-4.5	-4.1	-4.1	-4.1	-3.1	-2.3	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	
- TAX RATE	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	
OTHER/TAX ADJUSTMENTS	0.0	0.0	0.0	0.0	2.7	5.1	8.0	10.5	8.8	8.7	0.0	0.0	0.0	0.0	0.0	0.0	
CASH FLOW	**-20.6**	**-18.9**	**-18.9**	**-18.9**	**-11.3**	**-5.6**	**-0.2**	**2.3**	**0.6**	**0.5**	**-8.2**	**-8.2**	**-8.2**	**-8.2**	**-8.2**	**-8.2**	
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*-51%*	*-96%*	*-1164%*	*-72%*	*-20%*	*-1674%*	*0%*	*0%*	*0%*	*0%*	*0%*	
WACC (%)																**15.0**	
PERPETUAL GROWTH																	
NUMBER OF YEARS	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	
DISCOUNT FACTOR	1.00	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25	0.21	0.19	0.16	0.14	0.12	
DISC. CASH FLOW	**-20.6**	**-16.4**	**-14.3**	**-12.4**	**-6.4**	**-2.8**	**-0.1**	**0.9**	**0.2**	**0.1**	**-2.0**	**-1.8**	**-1.5**	**-1.3**	**-1.2**	**-1.0**	**NPV CHF M**
TOTAL DISCOUNTED CASH FLOWS																	-81
NPV AT 100% PROBABILITY	**100%**																**-81**

End of July 2023: Raxone (idebedone) global business in LHON completely divested to Chiesi. Chiesi assumes French reimbursement liability (EUR 25m). Santhera ceased all Raxone-related activities. SANN retains potential to get up to USD 10m in milestones or single-digit royalties upon approval in the US, and high-single digit royalties in other indications (OctE: not included in our valuation)

SUMMARY NPV MODELS

CHF M	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	
PRODUCT SALES (EU)	**0.0**	**8.4**	**22.2**	**40.7**	**68.6**	**96.4**	**120.7**	**132.3**	**132.0**	**131.6**	**131.2**	**130.7**	**130.3**	**104.3**	**52.1**	**26.1**	
US & ROW ROYALTY & PARTNERING INCOME	91.5	11.0	11.7	12.4	22.9	24.0	35.6	55.4	38.1	38.0	55.9	37.8	37.7	37.7	37.7	37.7	
TOTAL REVENUES	**91.5**	**19.4**	**33.9**	**53.1**	**91.5**	**120.4**	**156.2**	**187.7**	**170.0**	**169.6**	**187.1**	**168.6**	**168.1**	**142.0**	**89.9**	**63.8**	
TOTAL COGS	0.0	1.0	2.4	4.1	6.9	9.6	12.1	13.2	13.2	13.2	13.1	13.1	13.0	10.4	6.3	3.1	
GROSS PROFIT	**91.5**	**18.4**	**31.5**	**49.0**	**84.6**	**110.8**	**144.2**	**174.5**	**156.8**	**156.4**	**174.0**	**155.5**	**155.0**	**131.6**	**83.6**	**60.7**	
- GROSS MARGIN IN %	*100%*	*95%*	*93%*	*92%*	*93%*	*92%*	*92%*	*93%*	*92%*	*92%*	*93%*	*92%*	*92%*	*93%*	*93%*	*95%*	
TOTAL R&D (PROB. ADJ.)	19.0	15.0	12.0	12.0	8.0	6.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	
TOTAL SG&A (ADJ.)	27.0	32.0	39.0	42.0	41.0	40.0	41.0	42.0	43.0	44.0	45.0	46.0	47.0	38.0	25.0	16.5	
OTHER PAYMENTS (REVERAGEN, IDORSIA)	0.0	0.5	19.4	3.1	5.8	8.2	11.5	12.6	12.5	12.5	12.5	12.4	12.4	9.9	3.4	1.6	
EBIT	**45.5**	**-29.1**	**-38.9**	**-8.0**	**29.8**	**56.6**	**88.7**	**116.9**	**98.3**	**96.9**	**113.5**	**94.1**	**92.6**	**80.7**	**52.2**	**39.6**	
- EBIT MARGIN IN %	*NM*	*NM*	*NM*	*NM*	*33%*	*47%*	*57%*	*62%*	*58%*	*57%*	*61%*	*56%*	*55%*	*57%*	*58%*	*62%*	
TAXES	8.2	-5.2	-7.0	-1.4	5.4	10.2	16.0	21.0	17.7	17.4	20.4	16.9	16.7	14.5	9.4	7.1	
- TAX RATE	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	*18%*	
OTHER/TAX ADJUSTMENT	0.0	0.0	0.0	0.0	2.7	5.1	8.0	10.5	8.8	8.7	0.0	0.0	0.0	0.0	0.0	0.0	
CASH FLOW	**37.3**	**-23.9**	**-31.9**	**-6.6**	**27.1**	**51.5**	**80.7**	**106.4**	**89.5**	**88.2**	**93.1**	**77.1**	**76.0**	**66.1**	**42.8**	**32.5**	
- CHANGE IN %	*NM*	*NM*	*NM*	*NM*	*NM*	*90%*	*57%*	*32%*	*-16%*	*-1%*	*6%*	*-17%*	*-2%*	*-13%*	*-35%*	*-24%*	
WACC (%)																**15.0**	
PERPETUAL GROWTH																	
NUMBER OF YEARS	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	
DISCOUNT FACTOR	1.00	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25	0.21	0.19	0.16	0.14	0.12	
DISC. CASH FLOW	**37.3**	**-20.7**	**-24.1**	**-4.3**	**15.5**	**25.6**	**34.9**	**40.0**	**29.2**	**25.1**	**23.0**	**16.6**	**14.2**	**10.8**	**6.1**	**4.0**	**NPV CHF M**
TOTAL DISCOUNTED CASH FLOWS																	233
NPV FROM ABOVE (RISK-ADJUSTED)	**93%**																**216**

Risk-adjusted NPV Model - Summary

rNPV (CHF M)	NPV (100%)	RISK ADJUSTMENT	rNPV	PER SHARE (CHF)	IN %
VAMOROLONE USA (IN DMD)	170	100%	**170**	**8.3**	67%
VAMOROLONE EU (IN DMD)	119	90%	**107**	**5.2**	42%
VAMOROLONE ROW (IN DMD)	25	80%	**20**	**1.0**	8%
VAMOROLONE IN OTHER INDICATIONS	0	0%	**0**	**0.0**	0%
LONODELESTAT (PHASE I)	0	0%	**0**	**0.0**	0%
OTHER INCOME/COST (ADJ.)	-81	100%	**-81**	**-3.9**	-32%
TOTAL PRODUCTS/COST	233		**216**	**10.5**	85%
NET CASH (as of end 2022)	1		1	0.1	1%
EXCHANGEABLE NOTES (repaid in H2-23)	-28		-28	-1.4	-11%
PUBLIC CONVERTIBLE DEBT ('24)	-14		-14	-0.7	-5%
CASH FROM OPTIONS/WARRANTS*	27		27	1.3	11%
ASSUMED CAPITAL INCREASES (2024E/25E)	50		50	2.4	20%
EQUITY FAIR VALUE	**270**		**253**	**12.3**	**100%**

NO. OF SHARES ISSUED (M)	*12.559*	*incl. treasury shares*
TREASURY SHARES HELD	*1.995*	*(1.415m treasury shares used for Catalyst stake in Q3-23E)*
CURRENT SHARES OUTSTANDING	***10.564***	
NEW SHARES FOR CONV. DEBT (2024) - private (HB)	*1.677*	*conversion price CHF 5.00-10.00*
*NEW SHARES FOR WARRANTS**	*1.403*	*exercise price CHF 5.00-20.00*
*NEW SHARES FROM OPTIONS**	*1.339*	*exercise price CHF 0.00-1'126*
SUB-TOTAL	***14.983***	***fully diluted share count (excl. treasury shares)***
NEW SHARES FOR CAPITAL INCREASES (2024E/25E)	*5.556*	*assumed funding requirements until break-even (calculated at CHF 9/share)*
TOTAL NO. OF SHARES (M)	***20.538***	***used for rNPV calculation*** WACC: 15.0%
NEW SHARES FOR CONV. DEBT (2024) - public/listed	*0.452*	*conversion price CHF 30.3 - assume it will be redeemed - not included in share count*

SOURCE: OCTAVIAN
*assumed avg. strike price of CHF 10

Sensitivity to WACC (%)							
	12.0	13.0	14.0	**15.0**	16.0	17.0	18.0
CHF	14.9	14.0	13.1	**12.3**	11.6	10.9	10.3

Sensitivity to share price used for dilution (capital increases):						
	7	8	**9**	10	11	Price (CHF)*
CHF	11.4	11.9	**12.3**	12.6	12.9	**rNPV per share**

*Assumed share price to calculate the no. of new shares

OCTAVIAN

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