



# First 3 Months of 2023 Results and Business Update

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May 19, 2023

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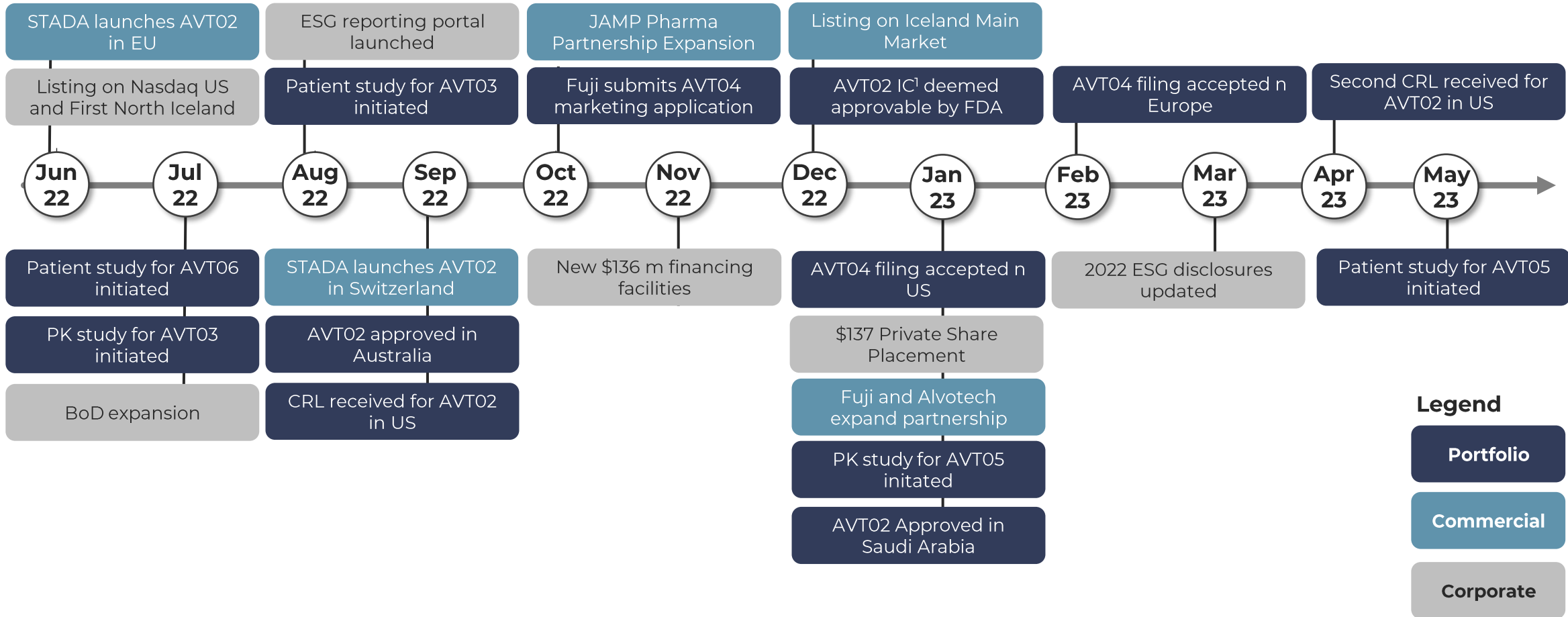
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# Robert Wessman

Chairman and Chief Executive Officer

# Continuing to Deliver on Strategy Since Listing in 2022



1. IC = Interchangeability; CRL was received noting site inspection requirement



# AVT02 Regulatory Update for U.S.

## What we know

2 BLA's for AVT02 for biosimilarity and interchangeability are approvable; Satisfactory site inspection is the only remaining requirement

1<sup>st</sup> BLA CRL<sup>1</sup> received April 2023, noting only deficiencies from the recent facility inspection

Responses to Form 483 from recent reinspection were submitted April 3, 2023, under evaluation

2<sup>nd</sup> BLA has goal date of June 28<sup>th</sup> 2023

AVT02 is sold in 17 global markets with no negative safety signals or concerns and approved in 42 markets

## Seeking Further Clarity

Evaluation of our responses provided to Form 483 submitted on April 3, 2023 and subsequent follow-ups (if needed)

Whether a re-inspection, either on-site or remote, would be required to gain approval for AVT02

## Next Steps

Meeting requested with OPMA<sup>2</sup> to gain further clarity regarding status of deficiencies noted in the recent inspection and evaluation of responses

Complete commitments made as part of company's response to Form 483; targeting June 1st as the date to complete all outstanding CAPA commitments related to commercial manufacturing and supply

Company intends to resubmit the biosimilar BLA for AVT02 after completing commitments made as part of the Form 483 response; expect a 6-month review, if needed, pending decision on June 28



# Anil Okay

Chief Commercial Officer

# Portfolio Update

Biosimilar Candidate	Reference Biologic	Therapeutic Area	Early Phase	Pre-clinical	Clinical Trial(s)	Filing	Approval	Launch	
<b>AVT02</b> high-concentration adalimumab	HUMIRA®	Immunology						<b>Approved by:</b> European Commission Health Canada MHRA, TGA	<b>Launched in:</b> Canada Europe (16)
<b>AVT04</b> ustekinumab	STELARA®	Immunology					<b>Filed in Major Markets</b>		
<b>AVT03</b> denosumab	PROLIA®/ XGEVA®	Immunology/ Oncology							
<b>AVT06</b> aflibercept	EYLEA®	Ophthalmology							
<b>AVT23*</b> omalizumab	XOLAIR	Respiratory							
<b>AVT05</b> golimumab	SIMPONI®/ SIMPONI ARIA®	Immunology							
<b>AVT16</b> vedolizumab	ENTYVIO®	Immunology							
<b>AVT33</b> pembrolizumab	KEYTRUDA®	Oncology							

# Commercial Updates

## Added global partnerships

Extended our agreement with Fuji Pharma to cover commercialization of new undisclosed biosimilar candidate in Japan

New partnership agreement with Polifarma to cover commercialization of AVT06 biosimilar candidate to Eylea® (aflibercept) in Turkey

We now have 18 distinct partners covering over 90 markets for our portfolio and pipeline.

## AVT02 launches continuing in 2023

AVT02 (adalimumab) biosimilar to Humira® in 17 markets to date, including 16 in Europe and Canada

Currently planning for additional launches in 7 markets in 2023; excluding the U.S. market pending regulatory clarity

## AVT04 Commercial Preparation

Working with our partners to launch AVT04, our proposed biosimilar to Stelara® (ustekinumab), at earliest allowable date

We believe Alvotech was first company to file marketing applications in a number of key markets

Anticipate being in a strong position globally to compete in ustekinumab market





# Joel Morales

Chief Financial Officer

# Q1 2023 Financial Highlights

## Cash and Liquidity

- Private placement and convertible bond raises completed during Q1 2023.
- \$116 million of cash on hand as of March 31<sup>st</sup>.
- Excludes \$25 million of restricted cash.

## Operating Performance

- Q1 2023 total revenue of \$16 million, versus \$1 million in Q1 2022.
- The Company is currently exploring options to raise additional capital to continue investing behind the platform & R&D.
- Alvotech intends to provide 2023 guidance after July 1<sup>st</sup>.

## Shares Outstanding

- 263.5 million shares outstanding as of March 31<sup>st</sup>.
- Includes 39.0 million of earnout shares not currently vested<sup>1</sup>.
- Excludes shares to be issued for certain programs and arrangements that are not yet settled as of March 31<sup>st</sup>.

<sup>1</sup> Includes 38.3 million Seller Earn Out Shares and 0.6 million Sponsor Earn Out Shares not yet vested as of March 31<sup>st</sup>.



An aerial photograph of a modern architectural complex. The central focus is a large building under construction, outlined with a dashed orange border. It features a flat roof with some construction materials and a glass facade. To its left is a completed building with a green roof and a large parking lot. To the right, several other buildings with green roofs are visible. The background shows a coastal town, a large body of water, and mountains in the distance under a cloudy sky.

Thank you





# Appendix

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# Reported to Adjusted Reconciliation – Q1 2023

\$ millions	Q1 2023			Q1 2022		
	Reported	Adjustment Entries	Adjusted	Reported	Adjustment Entries	Adjusted
Product Revenue	16	-	16	0	-	0
License and Other Revenue	-	0	0	-	0	0
Other Income	0	(0)	-	0	(0)	-
Cost of Product Revenue	(39)	1	(38)	(2)	-	(2)
R&D	(51)	19	(32)	(47)	(8)	(55)
G&A	(22)	6	(17)	(24)	13	(11)
<b>Operating Loss</b>	<b>(96)</b>	<b>26</b>	<b>(71)</b>	<b>(72)</b>	<b>5</b>	<b>(67)</b>
Share of Net Loss of JV	(1)	-	(1)	(1)	-	(1)
Finance Income	1	-	1	0	-	0
Finance Costs	(208)	179	(29)	(20)	-	(20)
Exchange Rate Differences	(2)	2	-	(2)	2	-
(Loss) Gain on exting. of fin. liab.	-	-	-	-	-	-
<b>Loss Before Taxes</b>	<b>(306)</b>	<b>207</b>	<b>(99)</b>	<b>(95)</b>	<b>7</b>	<b>(88)</b>
Income Tax Benefit	29	(4)	25	18	(1)	17
<b>Loss For The Period</b>	<b>(276)</b>	<b>202</b>	<b>(74)</b>	<b>(77)</b>	<b>6</b>	<b>(71)</b>
<b>Loss Per Share (in \$)</b>	<b>(1.24)</b>		<b>(0.33)</b>	<b>(0.43)</b>		<b>(0.39)</b>

## EBITDA:

<b>Operating Loss</b>	<b>(96)</b>	<b>26</b>	<b>(71)</b>	<b>(72)</b>	<b>5</b>	<b>(67)</b>
D&A	5	-	5	5	(0)	5
<b>EBITDA</b>	<b>(91)</b>	<b>26</b>	<b>(66)</b>	<b>(67)</b>	<b>5</b>	<b>(63)</b>

## Q1 2023 Adjustment Entries

<b>Cost of Product Revenue</b>	- \$1m charge related to long-term incentive plan (non-cash)
<b>R&amp;D</b>	- \$19m of one-time, Biosana accounts receivables reserve pertaining to the termination of AVT-23 (non-cash) - \$1m charge related to long-term incentive plan (non-cash) - (\$1m) IP litigation costs attributable to programs - reclassified from G&A
<b>G&amp;A</b>	- \$1m of one-time costs in connection with the Iceland main board listing - \$1m IP litigation costs attributable to programs - reclassified to R&D - \$4m charge related to long-term incentive plan (non-cash)
<b>Finance Cost</b>	- \$179m fair value adjustment on derivatives (non-cash)
<b>Exchange Rate Differences</b>	- Impact of exchange rate fluctuations (non-cash)
<b>Income Tax</b>	- Tax impact of discrete adjustments in jurisdictions where tax benefits are available

## Q1 2022 Adjustment Entries

<b>R&amp;D</b>	- (\$8m) IP litigation costs attributable to programs - reclassified from G&A
<b>G&amp;A</b>	- \$2m charge related to long-term incentive plan (non-cash) - \$8m of IP litigation costs directly attributable to programs - reclassified to R&D - \$3m of transaction costs incurred in connection with the OACB merger
<b>Exchange Rate Differences</b>	- Impact of exchange rate fluctuations (non-cash)
<b>Income Tax</b>	- Tax impact of discrete adjustments in jurisdictions where tax benefits are available