



# Q3 2023 YTD Results and Business Update

November 29, 2023

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# Robert Wessman

Chairman and Chief Executive Officer

# Recent Business Highlights

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## FDA inspection

FDA inspection expected to begin on January 11<sup>th</sup>, 2024. Successful inspection could lead to U.S. approval of AVT02, as an interchangeable biosimilar to high-concentration Humira® and U.S. approval of AVT04, as a biosimilar to Stelara®.

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## AVT04 approvals

AVT04 approved in Japan and Canada; Positive CHMP opinion in EU/EEA. Deemed approvable in U.S., subject to successful inspection in January 2024.

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## Kashiv Biosciences Transaction

Ensures continuity of the AVT23 program in multiple markets in EU, Australia Canada, UK and New Zealand.

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## Continued pipeline advance

AVT23 (also called ADL018), biosimilar candidate to Xolair®, in phase of confirmatory patient study. Alvotech now has 4 biosimilar candidates in active patient studies.

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# Anil Okay

Chief Commercial Officer

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## **Anticipate U.S. launch in 2024**

BsUFA goal date communicated by FDA is February 24, 2024. Only outstanding issue prior to approval is satisfactory reinspection in January 2024.

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## **Strong Competitive Profile**

Interchangeability with the prevalent form of adalimumab in the U.S. market, supports strong competitive position amongst the current biosimilar field.

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## **Potential for Exclusivity**

Potential for exclusivity for interchangeability of up to 12 months in the U.S. market if approved ahead of competition

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## **Market is still forming**

Limited biosimilar uptake thus far in the market; Opportunity for differentiated offering

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## First approved in major markets

AVT04 was the first biosimilar to Stelara® approved in Japan and Canada and the first to be recommended for approval by the European Medicines Agency.

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## Substantial addressable market

Stelara® global sales continue to grow, with total sales in the 12 months prior to September 30, 2023 exceeding \$10.5 billion<sup>[1]</sup>

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## US Strategy

License entry date for AVT04 in the U.S. is scheduled for Feb 21, 2025; Alvotech expects to gain interchangeability designation shortly after license entry date

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## Ex-US Strategy

Seeking to launch at the earliest possible time in each market; expects to be first to launch in a number of markets

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## Competition

Expect a less competitive environment globally

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[1] Source: J&J Quarterly Filings

# Kashiv Biosciences Transaction

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<b>Ensures Continuity</b>	Ensures continuity of the AVT23 program
<b>Leverages Existing Partnerships</b>	Alvotech has partnered with Advanz Pharma to commercialize AVT23 in the EU, Australia, Canada, UK and New Zealand.
<b>Demonstrates Flexibility of the Platform</b>	Demonstrates that Alvotech can deploy its platform either by developing and manufacturing inhouse or through in-licensing, leveraging its market access and regulatory expertise and global commercial network of partnerships.
<b>Strong Commercial Potential</b>	Combined sales of Xolair® in the EU, Australia, Canada, UK and New Zealand in 2022 were \$1.1 billion <sup>[1]</sup> .
<b>Favorable Competitive Profile</b>	Only one known filing in the EU

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[1] Source: IQVIA



# Alvotech is Pursuing a Strategically Selected Biosimilar Portfolio of Attractive Molecules

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> EU/EEA, Canada, UK, Turkey, Saudi Arabia, Egypt	<b>Launched in:</b> Canada EU/EEA countries
<b>AVT04</b> ustekinumab	STELARA®	Immunology						<b>Approved by:</b> Japan, Canada, CHMP	
<b>AVT03</b> denosumab	PROLIA® / XGEVA®	Bone Disease							
<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							
<b>AVT19</b> Undisclosed	Undisclosed	Undisclosed							
<b>AVT28</b> Undisclosed	Undisclosed	Undisclosed							
<b>AVT41</b> undisclosed	Undisclosed	Undisclosed							

HUMIRA is a registered trademark of AbbVie Inc.

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PROLIA AND XGEVA are registered trademarks of Amgen, Inc.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

ENTYVIO is a registered trademark of Millennium Pharmaceuticals, Inc.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp.



# Joel Morales

Chief Financial Officer

# Q3 2023 YTD Financial Highlights

## Cash and Liquidity

- Finalized financing facilities in July 2023, providing gross proceeds of ~\$140M.
- \$68.3 million of cash on hand as of September 30.
- Excludes \$25.2 million of restricted cash.

## Operating Performance

- September YTD 2023 product revenue of \$29.8m, increase of 169% versus prior year.
- \$8.0 million of milestone revenue recognized in Q3 primarily due to AVT23 development milestone.
- The company is actively pursuing licensing deals for early phase programs with strategic partners, providing upfront cash and milestones over time.

## Shares Outstanding

- 266.0 million shares outstanding as of September 30.
- Includes 39.6 million of earnout shares, of which 39.0 million not currently vested <sup>[1]</sup>.
- Excludes shares to be issued for certain programs and arrangements that are not yet settled as of September 30.

<sup>1</sup> Includes 38.3 million Seller Earn Out Shares and 0.6 million Sponsor Earn Out Shares not yet vested, and 0.6m vested Sponsor Earn Out Shares as of September 30.



# APPENDIX

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# Reported to Adjusted Reconciliation – Q3 2023 YTD

\$ millions	9M 2023			9M 2022		
	Reported	Adjustment Entries	Adjusted	Reported	Adjustment Entries	Adjusted
Product Revenue	29.8	-	29.8	11.1	-	11.1
License and Other Revenue	8.2	0.1	8.3	48.1	0.2	48.3
Other Income	0.1	(0.1)	-	0.2	(0.2)	-
Cost of Product Revenue	(104.4)	2.7	(101.7)	(35.4)	1.7	(33.7)
R&D	(152.8)	20.2	(132.6)	(133.1)	(10.7)	(143.8)
G&A	(58.6)	12.1	(46.5)	(156.5)	119.2	(37.3)
<b>Operating Loss</b>	<b>(277.7)</b>	<b>35.0</b>	<b>(242.7)</b>	<b>(265.6)</b>	<b>110.2</b>	<b>(155.4)</b>
Share of Net Loss of JV	(4.0)	-	(4.0)	(1.7)	-	(1.7)
Finance Income	46.4	(42.5)	3.9	97.3	(96.9)	0.4
Finance Costs	(107.8)	14.1	(93.7)	(69.2)	11.5	(57.7)
Exchange Rate Differences	0.9	(0.9)	-	13.6	(13.6)	-
(Loss) Gain on exting. of fin. liab.	-	-	-	17.8	(17.8)	-
<b>Loss Before Taxes</b>	<b>(342.2)</b>	<b>5.7</b>	<b>(336.5)</b>	<b>(207.8)</b>	<b>(6.6)</b>	<b>(214.4)</b>
Income Tax Benefit	67.1	(3.7)	63.4	14.8	0.5	15.3
<b>Loss For The Period</b>	<b>(275.1)</b>	<b>2.0</b>	<b>(273.1)</b>	<b>(193.0)</b>	<b>(6.1)</b>	<b>(199.1)</b>
<b>Loss Per Share (in \$)</b>	<b>(1.21)</b>		<b>(1.21)</b>	<b>(1.00)</b>		<b>(1.03)</b>
<b>EBITDA:</b>						
<b>Operating Loss</b>	<b>(277.7)</b>	<b>35.0</b>	<b>(242.7)</b>	<b>(265.6)</b>	<b>110.2</b>	<b>(155.4)</b>
D&A	17.5	-	17.5	17.8	(2.8)	15.0
<b>EBITDA</b>	<b>(260.2)</b>	<b>35.0</b>	<b>(225.2)</b>	<b>(247.8)</b>	<b>107.4</b>	<b>(140.4)</b>

## 9M 2023 Adjustment Entries

<b>Cost of Product Revenue</b>	- \$2.3m charge related to long-term incentive plan and \$0.3m loss on disposal of PPE (non-cash)
<b>R&amp;D</b>	- \$18.5m of one-time, Biosana accounts receivables reserve pertaining to the termination of AVT-23 (non-cash) - \$3.5m charge related to long-term incentive plan (non-cash) - (\$1.9m) IP litigation costs attributable to programs - reclassified from G&A
<b>G&amp;A</b>	- \$0.9m of one-time costs in connection with the Iceland main board listing - \$9.4m charge related to long-term incentive plan (non-cash) - \$1.9m IP litigation costs attributable to programs - reclassified to R&D
<b>Finance Income</b>	- (\$42.5m) fair value adjustment on derivatives (non-cash)
<b>Finance Costs</b>	- \$14.1m fair value adjustment on derivatives (non-cash)
<b>Exchange Rate Differences</b>	- (\$0.9m) impact of exchange rate fluctuations (non-cash)
<b>Income Tax</b>	- (\$3.7m) tax impact of discrete adj. in jurisdictions where tax benefits are available

## 9M 2022 Adjustment Entries

<b>Cost of Product Revenue</b>	- \$1.7m of non-cash impairment charges related to software
<b>R&amp;D</b>	- (\$11.1m) IP litigation costs attributable to programs - reclassified from G&A and \$0.4m impairment
<b>G&amp;A</b>	- \$106.6m of transaction costs incurred in connection with the merger, includes \$83.4m of non-cash listing service charge as per IFRS 2 - \$11.1m IP litigation costs attributable to programs – reclassified to R&D - \$0.9m of non-cash charge related to long-term incentive plan - \$0.7m of non-cash impairment charges related to software
<b>Finance Income</b>	- (\$96.9m) fair value adjustment on derivatives (non-cash)
<b>Finance Costs</b>	- \$5.0m Bond amendment (consent) fee related to the transaction close - \$6.5m loss on remeasurement of bonds (non-cash)
<b>Exchange Rate Differences</b>	- (\$13.6m) impact of exchange rate fluctuations (non-cash)
<b>(Loss) Gain on extinguishment</b>	- (\$17.8m) gain related to the conversion of shareholder loans (non-cash)
<b>Income Tax</b>	- \$0.5m tax impact of discrete adj. in jurisdictions where tax benefits are available

An aerial photograph of the Alvotech main facility in Reykjavik, Iceland. The image shows a large, modern industrial or office complex with several interconnected buildings. The buildings have a mix of grey and blue facades, with prominent glass facades on some sections. Many of the flat roofs are covered in lush green vegetation, indicating a green roof design. To the left, there is a large, paved parking lot filled with numerous cars. In the background, a residential area with houses and a large body of water (the ocean) are visible under a clear sky. The overall scene is bright and sunny, suggesting a clear day in summer.

Thank you

Alvotech main facility  
in Reykjavik Iceland, Summer 2023