

### SAVING LIVES IN RESISTANT TIMES

#### **April 2025**

April 2025 | BioVersys – Proprietary Material



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## **1. EXECUTIVE SUMMARY**

#### **TODAY'S PRESENTERS**





#### **Marc Gitzinger**

Chief Executive Officer, Founder

10+ years biotech executive & entrepreneur BEAM Alliance Board President; AMR Industry Alliance Board





#### **Hernan Levett**

#### **Chief Financial Officer**

30+ years finance and management experience; CFO of Spexis, CFO of Auris Medical; Group Controlling Head at Acino, VP of Europe Finance at InterMune





**Auris** Medical



### **COMPELLING INVESTMENT OPPORTUNITY**





# Significantly de-risked lead assets

Clear Phase 3 development path for lead asset Robust preclinical and clinical data package



#### Strong shareholder base

Cash position CHF 32.6 million as of December 31, 2024

# 600Ö

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# Clear commercial outlook and positioning

Focus on life threatening diseases Upside potential from changing reimbursement environment

#### SCIENCE

Assets in Clinical Phase 2 (BV100 – phase 3 ready), *incl. FDA QIDP designation* 

2 Preclinical assets

Discovery programs + platforms

#### FINANCE

- **CHF 93m** Total Equity money raised from leading investors
- +CHF 77m IPO SIX February 2025
  - CHF 21m Non-dilutive funding

**CHF 24m** Loan facility from the EIB and Basler Kantonalbank

#### CORPORATE

Credible, founder-led team with vast experience in developing antibacterial drugs

AMR a global health threat



Equity investment from Large Pharma GSK

Source: Company information.

### **COMPANY RESEARCH & DEVELOPMENT STRATEGY**

#### BV100 Phase 3 ready Alpibectir Tuberculosis: Hospital infections Phase 2 Multi-drug resistant Acinetobacter baumannii (VABP/HABP & BSI) TB-Meningitis **BV500 BV200** CF and COPD: Preclinical Atopic dermatitis Non-tuberculosis Staphylococcus aureus mycobacterial infection Early Stage (BV Discovery) Enhance existing drug profile Industry partnerships / Non-dilutive financing collaborations **Ansamycin Discovery Platform TRIC Platform**

Source: Company information. Note: CF: Cystic Fibrosis; COPD: Chronic Obstructive Pulmonary Disease; VABP: Ventilator Associated Bacterial Pneumonia; HABP: Hospital Acquired Bacterial Pneumonia; BSI: Blood Stream Infections; TRIC: Transcriptional Regulator Inhibitory Compounds.

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## **INNOVATIVE, DIVERSE AND DE-RISKED PIPELINE**



#### Next-Generation Antimicrobial Drugs, Two Proprietary Platforms

Program	Indication	R&D/Preclinical	Phase 1	Phase 2	Phase 3	Expected Key Catalyst	Commercial Rights	Designation
<b>BV100</b> Novel MoA Rifabutin IV form. <b>Ansamycin platform</b>	Hospital infections Acinetobacter baumannii (VABP/HABP & BSI)					Phase 3 FPFV: H2 2025	▼⁄	QIDP
Alpibectir New Antibiotic Class Eto-potentiator TRIC platform	Tuberculosis: • Multi-drug resistant • TB-Meningitis • TB-Meningitis					TBM Phase 2b: H1 2026 Pulmonary TB Phase 2a/b: H1 2025	С	QIDP Orphan Drug
<b>BV200</b> Anti-virulence <b>TRIC platform</b>	Atopic dermatitis Staphylococcus aureus					IND Filing: H1 2027	▼⁄	
BV500 Ansamycin platform	CF and COPD: Non-tuberculous mycobacteria infection CF AMR Syndicate RESPIRI					IND Filing: H2 2026	▼⁄	
BV Discovery	Targets undisclosed						▼∕	

Source: Company information. Note: Data as of September 06, 2024; VABP: Ventilator Associated Bacterial Pneumonia; HABP: Hospital Acquired Bacterial Pneumonia; BSI: Blood Stream Infections; Eto: Ethionamide; FDA QIDP: FDA Qualified Infectious Disease Product Designation: 5 years additional market exclusivity (until 2045 for BV100) and the possibility of fast-track approval; MOA: Mechanism of Action; IND: Investigational New Drug; CF: Cystic Fibrosis; COPD: Chronic Obstructive Pulmonary Disease.

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AMR (Anti-MICROBIAL RESISTANCE): MARKET OPPORTUNITY

# A MATTER OF TIME

Anti-Microbial Resistance On Track to Kill more People than all Cancers Together<sup>1</sup>

# 1.27M

deaths globally attributable to AMR<sup>2,5</sup>

# ~5M deaths globally associated with AMR<sup>2,5</sup>

Any surgery can become life-threatening

leading cause of death globally for the 9.8m patients receiving cancer chemotherapy is infection<sup>3</sup>

2nd

of hospitalized Covid-19 patients contracted bacterial superinfections<sup>4</sup>

~20%

Note: 1. Comparing all cancer-attributable deaths in 2014 vs. 2050 projections for AMR-attributable deaths, The Review on Antimicrobial Resistance, Chaired by Jim O'Neill, 2014; 2. Murray, C.J.L, et al. The Lancet VOLUME 399, February 12, 2022; 3. Elfaituri et.al. Journal of Clinical Oncology, May 26, 2019; 4. Muzuuza et.al. PLoS ONE, May 2021; 5. 2019 figures.

# SOLVING THE RIDDLE – SUSTAINABLE PROFITABILITY IN VERSYS TODAY'S REIMBURSEMENT SYSTEM



Source: Company information. Note: SoC: Standard of Care; UTI: Urinary Tract Infection; IAI: Intra-abdominal Infection; SSSI: Skin and Skin-Structure Infection; TB-M: Tuberculosis Meningitis; MDR: Muti-drug Resistant.

BioVersys' products are designed for time sensitive, life-threatening infections with limited available treatment options

## SOLVING THE AMR COMMERCIAL UPTAKE



#### Keys to Commercial Success

#### **BioVersys Approach**



Source: Company information. Note: 1. Zyvox and Cubicin; MRSA: Methicillin-resistant Staphylococcus aureus. UTI: Urinary Tract Infection; ABSSI: Acute Bacterial Skin and Skin Structure Infections; API: Active Pharmaceutical Ingredient; IDSA: Infectious Diseases Society of America; DRG: Diagnosis-related Group; NTAP: New Technology Add-on Payment; KOL: Key Opinion Leader.

Combining the right product, right indication, right clinical development strategy and right commercial setup delivers returns in AMR – addressing the unmet medical need that exists today

# **ANTIBIOTIC DE-RISKING OCCURS EARLIER THAN IN OTHER TAS** $\nabla$ BIOVERSYS



Source: 1. Wouters et.al., "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018", JAMA. 2020;323(9):844–853. doi:10.1001/jama.2020.1166. Note: As of September 06, 2024. TA: Therapeutic Area; PK: Pharmacokinetics; PD: Pharmacodynamics.

#### Greater probability of technical success for anti-infectives

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BV100:

Severe hospital infections caused by carbapenem resistant *Acinetobacter baumannii* 

### **BV100 TARGETING CARBAPENEM-RESISTANT ACINETOBACTER (CRAB) IN PNEUMONIA**



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## WORKHORSE ANTIBIOTIC CLASS IS FAILING

>50% Overall Resistance Against Carbapenems (CRAB)



Source: Management estimate. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet 2022; 399: 629–55 Modeled estimates based on 2019 actuals, by the 'Antimicrobial Resistance Collaborators'. "BV100 Major Markets" include US, France, UK, Italy, Germany, Spain, Austria, Portugal, Switzerland, Sweden, Belgium, Czech Republic, Denmark, Finland, Greece, Netherlands, Norway and Poland. "BV100 China and BV100 Emerging Markets" include Urban China (as defined by the DRG), Brazil, Mexico, South Korea and Turkey.

#### BV100 addresses an urgent call for action

# **BV100 – A DIFFERENTIATED DRUG WITH A NEW MOA** $\nabla$ BIOVERSYS



Source: Company information. Note: MoA: Mode of Action; FhuE: Membrane protein acting as a receptor; MDR: Multidrug resistant; SoC: Standard of Care. 1. Due to QIDP designation by FDA received in May 2019.

## **SUMMARY OF PHASE 1 CLINICAL STUDIES**



7 Phase 1 Studies Have Been Completed (SAD, MAD, 2xDDI, RI, HI, BAL)



BV100 was considered safe and well tolerated



No dose adjustment of BV100 was necessary for patients with all degrees of impaired renal function



No dose adjustment of BV100 was necessary for patients with mild, moderate or severe hepatic impairment is anticipated



BV100 was a mild inducer of CYP3A4 enzyme. The midazolam (index substrate) AUC decreased by <50%<sup>1</sup>. No dose adjustment is anticipated



The mean  $C_{max}$ ,  $AUC_{0-24}$  and  $AUC_{0-inf}$  of rifabutin were **14%**, **26%** and **69% higher** after BV100 was administered with Itraconazole (index inhibitor) compared to BV100 alone. **No dose adjustment** is anticipated



BV100 shows very good exposure in the ELF, with **mean ratios calculated as CELF/Cplasma and AUCELF/AUCplasma of 51 and 36**, respectively, underscoring the very good distribution of rifabutin into the lung

Source: Company information.

Note: 1. Rifampicin results in a 99% reduction; 2. As of September 30, 2024, including Phase 2 patients. q12h: twice daily dosing; AUC: Area Under the Curve; SAD: Single Ascending Dose; MAD: Multiple Ascending Dose; DDI: Drug-drug interaction; RI: Renally Impaired; HI: Hepatic Impaired; BAL: Bronchoalveolar lavage; Cmax: Peak drug concentration; CYP3A4: Cytochrome P450 3A4.

# BV100 is considered safe and well tolerated, dosing q12h without any dose adjustments likely, 236<sup>2</sup> people dosed so far

#### **PHASE 2 TRIAL IN VABP**

#### Patients with Suspected or Confirmed Acinetobacter VABP



Source: Company information. Note: VABP: Ventilator Associated Bacterial Pneumonia; PK: Pharmacokinetics; q12h: Twice-daily dosing; Polymyxin B: Will be dosed according to international consensus guidelines; AE: Adverse Event; FPFV: First Patient First Visit; DSMB: Data and Safety Monitoring Board; LPLV: Last Patient Last Visit; 1. Treatment failure, VABP due to colistin-resistant Acinetobacter or patients with known intolerance to colistin.

# The Phase 2 study was used to determine the safety and PK of BV100 to enable a final dose for the Phase 3 trial in order to de-risk the program



### **OVERVIEW OF ADVERSE EVENTS**



#### Safety population<sup>1</sup>

	Pa	Part B	
	BV100 + Poly B (N=21)	BAT (N=10)	BV100 + BAT (N=8)
TEAE	19 (90.5%) 56	7 (70%) 22	8 (100%) 30
TEAE (Grade 3/4/5) <sup>2</sup>	13 (61.9%) 27	7 (70%) 11	7 (87.5%) 12
Serious TEAE	8 (38.1%) 11	6 (60%) 8	3 (37.5%) 4
Fatal TEAE	6 (28.6%) 6	6 (60%) 6	3 (37.5%) 3
SUSAR	0 (0%) 0	0 (0%) 0	0 (0%) 0
AESIs	0 (0%) 0	0 (0%) 0	0 (0%) 0
TEAE leading to BV100 discontinuation <sup>3</sup>	2 (9.5%) 2	NA	1 (12.5%) 1
Treatment-related TEAE (to BV100)	0 (0%) 0	NA	0 (0%) 0
Treatment-related TEAE (to Polymyxin B)	6 (29%) 6	NA	NA
Treatment-related SAE / deaths (to BV100)	0 (0%) 0	NA	0 (0%) 0
Treatment-related SAE / deaths (to Polymyxin B)	0 (0%) 0	NA	NA

<sup>1</sup>Safety population includes patients randomized (part A) and assigned (part B) who received at least one dose of study treatment.

<sup>2</sup>grade 3 = severe AE, grade 4 = Life-threatening AE, grade 5 = AE result in death.

<sup>3</sup>Two patients in BV100 + Poly B arm experienced TEAE leading to BV100 discontinuation. The BV100 discontinuation was due to patient death rather than the TEAE itself, all BV100 doses were administered before death occurred.

TEAE = Treatment Emergent Adverse Event; SAE = Serious Adverse Event; AESI = Adverse Event of Special Interest; SUSAR = Suspected Unexpected Serious Adverse Reaction; BAT = Best Available Therapy; N = total number of subjects in the Safety Population. Results given as "n (%) E" where n=number of subjects with events, (%)=percentage, E=number of events.

#### BV100 is generally safe and well tolerated and safety profile is consistent with rifabutin

#### **BV100 SHOWS CLEAR SURVIVAL BENEFIT**

BV100 Part A versus BAT: Day 14 and Day 28 ACM in micro-ITT\* (LPLV 27.09.2024)



#### \* Positive, rapid diagnostic test showing the presence of A. baumannii

Source: Company information. Note: 1. The data is preliminary as the study is ongoing; Data as of August 8, 2024. 2. BAT failure; pan-drug resistant. ACM: All-cause Mortality; ITT: Intention to Treat; AB: Antibiotics; SOFA: Sequential Organ Failure Assessment; CPIS: Clinical Pulmonary Infection Score; PaO2: Partial pressure of oxygen; FiO2: Fraction of inspired oxygen; AEs: Adverse Events; SAEs: Serious Adverse Events; BAT: Best Available Therapy. \*Reference FDA briefing document 04.17.23

Phase 2 data suggest BV100 has a good survival benefit compared to best available therapy (BAT) in the mITT population. For comparison Xacduro showed a 12-13% benefit compared to colistin<sup>+</sup>

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# **IMPROVED MICROBIOLOGICAL AND CLINICAL RESPONSE V** <sup>B</sup> <sup>I</sup> <sup>O</sup> <sup>V</sup> <sup>E</sup> <sup>R</sup> <sup>S</sup> <sup>Y</sup> <sup>S</sup> **WITH BV100**

BV100 Part A versus BAT: Carbapenem-resistant micro-ITT<sup>1</sup>



<sup>1</sup>Carbapenem-resistant Acinetobacter m-ITT population (Primary efficacy analysis population). <sup>2</sup>Microbiological favorable response = eradication or presumed eradication; <sup>3</sup> Clinical cure defined as at ToC (7 ± 2 days after End of Treatment). <sup>4</sup> Reference FDA briefing document 04.17.23.

BAT = Best Available Therapy ; ToC = Test of Cure ; ITT = Intend to Treat ; EOT= End of Treatment.

Phase 2 data suggest BV100 has a good microbiological response and clinical cure benefit compared to BAT. For comparison Xacduro showed a 21.6% and 26% benefit<sup>4</sup>

**BIOVERSYS - PROPRIETARY MATERIAL** 

## PROPOSAL FOR A GLOBAL PHASE 3 TRIAL (CRAB: VABP, HABP, BSI)

**Regulatory trial:** A global Phase 3 Non-inferiority trial comparing BV100 versus Colistin



**Clinical differentiating trial-**> A global Phase 2b study comparing BV100 versus Best Available Therapy (BAT)





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Primary endpoint

• 28-Day ACM

Safety endpoint

Overview of AEs

#### Secondary Efficacy endpoints

- 14-day ACM
- Clinical cure rate
- Ventilator free days
- Time in ICU
- Time in Hospital

Trial design is validated either by CHMP or through precedents

Note: VABP: Ventilator Associated Bacterial Pneumonia, HABP: Hospital Associated Bacterial Pneumonia, BSI: Blood Stream Infection; AE: Adverse Event, ACM: All Cause Mortality; ICU: Intensive Care Unit; CHMP: Committee for Medicinal Products for Human Use.

Global Phase 3 trial design generally agreed with the FDA and EMA

# ANTIBIOTIC DE-RISKING OCCURS EARLIER THAN IN OTHER TAS

Experience in Antibiotic Development Shows Important De-Risking Events Precede Late-Stage Efficacy Studies



Source: 1. Wouters et.al., "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018", JAMA. 2020;323(9):844–853. doi:10.1001/jama.2020.1166. Note: 2. As of September 30, 2024; 3. Two of the studies are ongoing; TA: Therapeutic Area; PK: Pharmacokinetics; PD: Pharmacodynamics; API: Active Pharmaceutical Ingredient.

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#### **ESTIMATING THE MARKET FOR BV100**





Source: Company. 1. See Appendix - Market Definitions for a list of countries within each market; 2. DRG/Clarivate 2021 and epidemiology publications, including high and low risk infections; 3. Management estimate. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet 2022; 399: 629–55 Modeled estimates based on 2019 actuals, by the "Antimicrobial Resistance Collaborators"; 4. Based on duration of standard treatment procedures and BioVersys clinical protocol; 5. Akceso (3<sup>rd</sup> party) pricing study and partnership discussions, under current reimbursement environment. Note: 6. Calculated as the product of confirmed CRAB incidence, estimated treatment duration and daily net treatment price per geography. Note: CRAB: carbapenem-resistant strains.

#### **PEAK SALES GUIDANCE FOR BV100**

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Source: Company. 1. See "Appendix - Market Definitions" page for a list of countries within each market; 2. DRG/Clarivate 2021 and epidemiology publications, including high and low risk infections (2027 projected incidence); 3. 2027 estimates of CRAB incidence based on Management assumptions of CRAB as a percent of AB infections supported by the following publications: U.S (Spellberg, 2013), EU17 (Ayobami, 2020), Japan (Ikeda, 2011), China (DRG) and Emerging Markets (Kim, 2018). The remainder of diagnosed A. baumannii cases are assumed to be Empiric therapy; 4. Akceso (3<sup>rd</sup> party) pricing study and partnership discussions, under current reimbursement environment. 5 Peak penetrations per geography are Management assumptions. 6. Assumes peak sales reached 9-years after product launch in each geography. Note: CRAB: carbapenem-resistant strains of Acinetobacter baumannii.

#### **BV100 – DIFFERENTIATED MEDICAL BENEFITS**



7 Clinical Trials Completed / Ongoing: Dosed in 236 <sup>1</sup> People							
Company	Product	Distributes Well into Lung	No Pre-existing Resistance	Mode of Action	Approved API with Good Safety	Synergy with SoC	Development Phase
<b>▼</b> B I O V E R S Y S	BV100			NEW	$\checkmark$		Phase 3 ready
Generic	Polymyxin / Colistin (Standard of Care)	×		N/A	Renal Tox	×	MARKETED
	XACDURO (Sul-Dur)			OLD	$\checkmark$	×	MARKETED
Roche	RG6006	?	?	NEW	×	?	1
	MEM-ANT3310			OLD	×	?	1
Polymyxin Analogs							
	MRX-8			OLD	×		1
SPER® THERAPEUTICS	SPR 206			OLD	×		12
BrijBiosciences	QPX9003			OLD	×		1
Omnix Medical	OMN-6	?		NEW	×	?	1b/2a

Source: Company estimate based on public materials as of September 2024; indicative only. Note: 1. As of September 30, 2024; 2. Phase 2-ready.

#### BV100 is well differentiated vs. its competitors in development

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Alpibectir:

Pulmonary and

meningeal Tuberculosis

## **BIOVERSYS TACKLING THE TOP PRIORITY SUPERBUGS**



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#### **ALPIBECTIR – NEW MARKET OPPORTUNITIES**

Emerging Markets Need New TB Treatments Urgently

World Health Organization

Estimated TB incidence rates, 2022



#### Source: WHO Global TB Report 2023

"Alpibectir Major Markets" includes Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, Norway, Portugal, South Korea, Spain, Sweden, Switzerland, UK, USA; China & Alpibectir Emerging Markets" includes China, Belarus, Brazil, Bulgaria, Estonia, Hungary, Kazakhstan, Latvia, Lithuania, Mexico, Poland, Romania, Russian Federation, Algeria, Angola, Argentina, Egypt, Georgia, Indonesia, Kyrgyzstan, Malaysia, Morocco, Philippines, South Africa, Thailand, Ukraine, Uzbekistan, Vietnam, Afghanistan, Armenia, Azerbaijan, Bangladesh, Benin, Bolivia, Burkina Faso, Burma, Cambodia, Cameroon, Colombia, Cote D'Ivoire, DR Congo, Ethiopia, Ghana, India, Kenya, Madagascar, Malawi, Moldova, Mozambique, Nepal, Nigeria, Pakistan, Soudan, Tajikistan, Tanzania, Uganda, Zimbabwe and Zambia.

## **ETO BIOACTIVATION VIA A NOVEL PATHWAY**

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Source: Company information. Note 1. Patent filed in 61 countries; Eto: Ethionamide; Pto: Prothionamide; InhA: A gene encoding a target for isoniazid and ethionamide in Mycobacterium tuberculosis.



The study has completed recruitment, and the data is being analysed

# **PHASE 2A: HUMAN PROOF OF CONCEPT ACHIEVED**

AlpE Outperforms Eto Alone and Shows Comparable Activity to INH Preliminary Results<sup>1</sup>



- GSK
- Efficacy in time-to-positivity (TTP) from start to end of treatment
- The higher the TPP, the bigger is the EBA
- EBA studies are not statistically powered but identify clear trends
- Full topline data
- AlpE was well tolerated in the study

Source: Company information.

Note: 1. Data extract from March 2024: Efficacy data from PartA was QCed, efficacy data from PartB is not QCed yet. EBA: early bactericidal activity; TTP: time to sputum culture positivity; Eto: Ethionamide; INH: isoniazid. AlpE: alpibectir/Eto; Qced: quality-controlled; TB: tuberculosis; CSF: cerebrospinal fluid.

Alpibectir (first in class) delivered proof of concept in human. The combination of AlpE has the potential to become the fastest bactericidal TB drug, overcoming resistance and with exposure in the CSF

#### $\nabla$ **BIOVERSYS** ESTIMATING THE MARKET FOR ALPIBECTIR China & Emerging Markets<sup>1</sup> Major Markets<sup>1</sup> Pulmonary TB - Isoniazid Mono-Resistant Tuberculosis (INH Mono-Indication Overview Resistance TB), Multi-Drug Resistant Tuberculosis (MTR-TB); TB-Meningitis (TBM) # of Tuberculosis Cases (2028 Projected Incidence)<sup>2</sup> >10.4m >50k ~12% **Pulmonary TB** ~17 INH Mono-Resistance TB + MDR-TB + TBM Incidence<sup>3</sup> TBM ~2% ~4% Estimated Treatment Duration<sup>4</sup> 180 Days Estimated Daily Net Treatment Price by Country<sup>5</sup> ~\$130 - \$150

Estimated Total Addressable Market Potential ~\$1.1bn<sup>6</sup> (2028)

Note: 1. See "Appendix - Market Definitions" page for a list of countries within each market; 2. Projected incidence derived from WHO databases and considers certain assumptions from Management; 3. Management assumptions for 2028 incidence of INH Mono-Resistance TB derived from the following epidemiology publications: U.S (lqbal, 2012), Other High Income (Van der Werf 2014), China (Xiao-chun He in Medicine 2015) and Other Upper/Mid Income Countries (Wang 2014 in PLOSone) and Mid to Low Income Countries; (Henkins 2011 in PLOSone, 2018). Management assumptions for 2028 incidence of MDR-TB derived from the following epidemiology publications: China (L Wang et al, 2014), All other markets: (WHO Global TB report 2022). Management assumptions for 2028 incidence of TB-Meningitis derived from the following epidemiology publications: U.S and Other High-Income Counties (Nguyen et al, 2014), All other markets (Vanino et al, Flores et al); 4. Official WHO suggestion for treatment regimes; 5. Management estimates based on current average per market treatment costs, given current reimbursement environment. 6. Calculated as the product of confirmed incidence, estimated treatment duration and daily net treatment price per geography.

### **PEAK SALES GUIDANCE FOR ALPIBECTIR**



#### INH-Resistant | MDR | TBM

	Major	r Markets <sup>1</sup>	China & Emerging Markets <sup>1</sup>			
Geography	United States	Other High Income Countries	China	Other Upper / Mid Income Countries <sup>1</sup>	Mid / Low Income Countries	
Est. # of TB cases <sup>2</sup>	7k	43k	645k	239k	>9.5m	
INH-Resistant Rate   MDR Rate   TBM Rate <sup>3</sup>	7.5%   4.5%   2.0%	7.5%   4.5%   2.0%	12.5%   6.0%   4.0%	12.5%   4.5%   4.0%	12.5%   4.5%   4.0%	
Pricing Range <sup>4</sup>	Benchmarked against bedaquillin	Benchmarked against bedaquillin	Benchmarked against bedaquillin	Benchmarked against bedaquillin	Subject to NGO guidelines	
Peak Market Share: INH- Resistant   MDR   TBM <sup>5</sup>	~50%   ~60%   ~60%	~50%   ~60%   ~60%	~35%   ~44%   ~44%	~35%   ~33%   ~33%	~35%   ~15%   ~15%	
Peak Sales by Geography <sup>6</sup>	~\$15m	~\$75m	~\$110m	~\$30m	~\$170m	
Total Peak Sales <sup>6</sup>			~\$400m	Expec	ted 50% share of peak sales with 🕞 S	

#### Peak market share potential CRAB High risk | Empiric | CRAB Low risk

Source: Company. Note: 1. See "Appendix - Market Definitions" page for a list of countries within each market; 2. Projected incidence derived from WHO databases and considers certain assumptions from Management; 3. Management assumptions for 2028 incidence of INH Mono-Resistance derived from the following epidemiology publications: U.S (ląbal, 2012), Other High Income (Van der Werf 2014, China (Xiao-chun He in Medicine 2015) and Other Upper/Mid Income Countries (Wang 2014 in PLOSone) and Mid to Low Income Countries; (Jenkins 2011 in PLOSone, 2018); Management assumptions for 2028 incidence of MDR-TB derived from the following epidemiology publications: China (L Wang et al, 2014), All other markets: (WHO Global TB report 2022); Management assumptions of TB-Meningitis derived from the following epidemiology publications: U.S and Other High-Income Countries (Nguyen et al, 2014), All other markets (Vanino et al, Flores et al); 4. Management estimates based on current average per market treatment costs, given current reimbursement environment; 5. Peak penetrations per geography, for treatment of INH-Resistant, MDR, and TBM are Management assumptions; 6. Assumes peak sales reached 7-9 years after product launch in each geography.

# TB PARTNERSHIP WITH GSK EXTENDED TO REACH PATIENTS IN NEED



Comple	eted	In Progress	Next Steps
Phase 1	Phase 2a	Phase 2	Phase 3
<ul> <li>Phase 1 (Complete): Study to investigate the safety, tolerability, PK in healthy volunteers (NCT04654143)</li> </ul>	<b>Phase 2a, AlpE-TB (ongoing):</b> Study to evaluate the EBA, safety and tolerability of Eto alone and in combination with Alpibectir administered orally to adults with newly diagnosed, rifampicin and isoniazid susceptible pulmonary TB (NCT05473195)	TBM DIOVERSYS Phase 2 TBM (in planning): Study to evaluate the PK, safety and preliminary efficacy of AlpE in TBM patients in the treatment of TBM	<ul> <li>TBM offers potential for a small Phase 3 study based on unmet medical need and LPAD</li> <li>Based on exposure and efficacy from Phase 2 studies, label should include TBM and</li> </ul>
• Eto-PK (Complete): Study to investigate the PKs of Eto and the active metabolite Eto-SO in patients on TB treatment (NCT05258877)		Pulmonary TB	<ul> <li>pulmonary TB</li> <li>AlpE offers unique positioning in regimens based on its fast bactericidal activity</li> <li>TBM &amp; MDR pathway elicible fore priority</li> </ul>
		studies with AlpE in combination with other anti-TB drugs in patients with pulmonary TB	eligible for a priority review voucher <sup>1</sup> after Phase 3 with estimated

Source: Company information. Note: AlpE: alpibectir/Eto; EBA: early bactericidal activity; Eto: Ethionamide; Eto-SO: Ethionamide-sulfoxide; MDR: multi-drug resistant; TBM: TB Meningitis; PTB: Pulmonary TB; LPAD: Limited population antibacterial drug. 1. FDA award for tropical diseases/illnesses related to public health emergencies; 2. Management assumption based on median purchase price of 3rd party vouchers from 2009-2019.

value of ~\$100M<sup>2</sup>

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Next generation candidates & discovery platform
# **DISCOVERY PLATFORMS AND OTHER PIPELINE ASSETS**

#### **BV200 Overview**

Phase	Preclinical			
Indication	Atopic dermatitis (mild – moderate)			
МоА	Topical treatment – inhibits AgrA (accessory gene regulator A) and toxins production in <i>S.aureus</i> , preventing skin damage and flares			
Platform	TRIC			
Data-to-date	Preclinical data – <i>in vivo</i> efficacy (mouse models)			
Next Milestone	Topical formulation suitable for preclinical tox			

#### **TRIC Platform**

Infant with Atopic dermatitis





#### Source: Nature, Biopharm; Deal. 2021. Note: NCE: New chemical entity; Adapted from Campbell et al. Cell. 2001 mar 21;104(6): 901-12.

#### **BV500 Overview**

Phase	Preclinical		
Indication	Non-tuberculous Mycobacteria (NTM) infections		
МоА	Oral treatment – Novel NTM focused ansamycin class NCEs		
Platform	Ansamycin		
Data-to-date	Preclinical data – <i>in vitro</i> efficacy		
Next Milestone	Selection of optimized Lead		

#### **Ansamycin Platform**





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### AMR – upside potential

# GOOD PROGRESS HAS BEEN MADE WITH A RANGE OF VERSYS INCENTIVES PILOTED ACROSS MAJOR MARKETS



Source: AMR Solutions, Center for Global Development, Charles River Associates; Policy solutions to commercial challenges in the fight against Antimicrobial Resistance, Charles River Associates; CCA CAC Overcoming Resistance, Expert Panel on Antimicrobial Availability. Note: 1. 118th Congress 1st Session Senate of the United States, April 2023; 2. Range is defined by unmet medical need addressed.

# **BIOVERSYS OPPORTUNITY**





Note: 1. Numbers based on management assumptions, see p. 41, 42, 53 and 54 of this deck; 2. FDA award for tropical diseases/illnesses related to public health emergencies; 3. Management assumption based on median purchase of third-party vouchers from 2009-2019; 4. Prosthetic Joint Infections (PJI) Osteomyelitis. NTM: Non-tuberculous mycobacteria; MSSA: Methicillin-Sensitive Staphylococcus aureus; MRSA: Methicillin-resistant Staphylococcus aureus.

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Financials

## **PROFIT AND LOSS – DECEMBER 31, 2024**

# **V** B I O V E R S Y S

### in CHF million (based on consolidated IFRS financial statements)



- Other operating income includes grant income as well as research tax credits and remained at the same level compared to prior year.
- Lower R&D expenses for the year 2024 mainly due to fewer studies being conducted in the year 2024, as most BV100 phase 1 studies have been completed.
- Higher G&A expenses due to higher expenses for share-based payments and consultancy services (mainly IPO related)
- Higher finance result for the year 2024 mainly due to the change in the fair value measurement of the warrants (CHF 0.6 million) and the net foreign exchange gains/losses (CHF 0.3 million), partially compensated by an increase of interest expenses due to the disbursement of the 2nd EIB loan tranche in July 2023 (CHF 0.3 million).

# **BALANCE SHEET - DECEMBER 31, 2024**

# **V** B I O V E R S Y S

### in CHF million (based on consolidated IFRS financial statements)



- Current assets comprise of cash and cash equivalents of CHF 26.6 million, current financial assets of CHF 6.0 million as well as prepaid expenses and other receivables of CHF 1.8 million.
- Equity increased by CHF 2.1 million mainly due to the capital increase of the Series C extension (CHF 14.7 million), the Conversion of the GIBF Investment into shares of BioVersys AG in December 2024 (CHF 5.2 million) and the reduction by the total net loss for the period (CHF 18.7 million).
- Non-current liabilities decreased mainly due to the reclassification of the BKB loan to current liabilities (CHF 2.9 million), partially equalized by additional interest expenses accrued for the EIB loan (CHF 0.9 million).
- Higher current liabilities mainly due to the reclassification of the BKB loan (CHF 2.9 million), additional accruals for services in relation with the IPO (CHF 0.7 million) and the decrease of prepayments for the Series C extension (CHF 2.8 million) which were converted into equity in Q2 2024.

# CASH FLOW – DECEMBER 31, 2024



in CHF million (based on consolidated IFRS financial statements)



- Cash and cash equivalents (CHF 26.6 million) plus current financial assets (CHF 6.0 million) resulted in a cash position of CHF 32.6 million as of the end of 2024.
- Cash flow from operating activities was mainly driven by progression of the clinical trials for our lead project BV100 and working capital adjustments.
- Cash outflow from investing activities is related to the increase of short-term deposits with original maturities over three months (classified as current financial assets) in the year 2024.
- Cash flow from financing activities includes mainly proceeds on issue of shares (Series C extension) of CHF 14.7 million, the GIBF investment of CHF 5.1 million (capital increase by non-controlling interests) and the transaction costs of CHF 0.4 million.

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### **Closing observations**

# **INVESTING IN BIOTECH**

Managing risk – creating upside

**Known API** 



- Well understood safety
- Clear Mode of Action
- Killing bacteria really fast
- Clear clinical endpoints that can be measured



- Excellent safety in trials, as expected
- High concentrations of drug in target organ (lung)
- Clear clinical benefit- reducing mortality
- Clinicians in trial "want" to use BV100



### Execution



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- Phase 3 path generally agreed with regulators and precedent exists
- Endpoints allow commercial differentiation for reimbursement
- "easy to use" in ICU setting, positive feedback from physicians
- Company fully financed to deliver clinical results on Phase 3

### **BV100:** Addressing AMR indication with limited/no treatment options with a clear path to success

### **UPDATED WHO PRIORITY PATHOGEN LIST 2024**





Table A2.11. Pathogens rated according to level of treatability

High	High-medium	Medium	Medium-low	Low
MR S. aureus	FQR Shigella spp.	3GCR E. coli	CR K. pneumoniae	CR A. baumannii
Macro-R Group A Streptococci	FQR nontyphoidal Salmonella	3GCR K. pneumoniae	Carbapenem-R E. coli	RR-TB
Macro-R S. pneumoniae	Ampi-R H. influenzae	VR E. faecium	FQR Salmonella Typhi	
	Pen-R Group B Streptococci	FQR N. gonorrhoeae	CR P. aeruginosa	
		3GCR Enterobacter spp.	CR Enterobacter spp.	
		3GCR Citrobacter spp.	3GCR N. gonorrhoeae	
		3GCR Proteus spp.		
		3GCR Serratia spp.		
		3GCR Morganella spp.		

FQR, fluoroquinolone-resistant; 3GCR, third-generation cephalosporin-resistant Enterobacterales; CR, carbapenem-resistant; Pen-R, penicillin-resistant; VR, vancomycin-resistant; Macro-R, macrolide resistant ; Ampi-R, ampicillin-resistant; RR-TB rifampicinresistant tuberculosis

Source: WHO Bacterial Priority Pathogens List, 2024: bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance.

# BioVersys pipeline addresses with two clinical assets the two most difficult to treat priority pathogens of the world

# **COMPELLING INVESTMENT OPPORTUNITY**



Leading the Fight to Overcome Life-threatening Infectious Diseases



Note: 1. Based on management assumptions, see pp. 41, 42, 53 and 54 of this deck of this presentation.

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Q&A



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