



Immunic
THERAPEUTICS

Immunic Therapeutics

Fourth Quarter and Year End 2022 Financial Results and Corporate Update

NASDAQ: IMUX | February 23, 2023

Cautionary Note Regarding Forward-Looking Statements

→ This presentation contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These include statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Immunic undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

→ Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Immunic’s plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing of initiation of Immunic’s planned clinical trials; the potential for IMU-838 and the Company’s other product candidates to safely and effectively target and treat the diseases mentioned herein; the impact of future preclinical and clinical data on IMU-838 and the Company’s other product candidates; the availability or efficacy of Immunic’s potential treatment options that may be supported by trial data discussed herein; expectations regarding potential market size; the timing of the availability of data from Immunic’s clinical trials; the timing of any planned investigational new drug application or new drug application; Immunic’s plans to research, develop and commercialize its current and future product candidates; Immunic’s ability to successfully collaborate with existing collaborators or enter into new collaboration agreements, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Immunic’s product candidates; Immunic’s commercialization, marketing and manufacturing capabilities and strategy; Immunic’s ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Immunic’s competitors and industry; the impact of government laws and regulations; COVID-19 and the armed conflict in Ukraine; Immunic’s ability to protect its intellectual property position; Immunic’s listing on The Nasdaq Global Select Market; expectations regarding the capitalization, resources and ownership structure of the company; the executive and board structure of the company; Immunic’s estimates regarding future revenue, expenses, capital requirements and need for additional financing; the nature, strategy and focus of the company; and the other risks set forth in the company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission.

→ Forward-looking statements included in this presentation are based on information available to Immunic as of the date of this presentation. Immunic does not undertake any obligation to update such forward-looking statements except as required by applicable law.



Agenda

Fourth Quarter and Year End 2022 Financial Results and Corporate Update

01 Fourth Quarter 2022 and Subsequent Highlights

02 Financial and Operating Results

03 Anticipated Clinical Milestones

04 Q&A Session

05 Summary and Highlights



01

Fourth Quarter 2022 and Subsequent Highlights

October: Closed USD 60 Million Private Placement, Extending Cash Runway Into Q4/2024

Summary

- Private investment in public equity (“PIPE”) financing
- Aggregate of 8,696,552 shares of common stock at a price of \$4.35 per share, and pre-funded warrants to purchase up to an aggregate of 5,096,552 shares of common stock at a purchase price of \$4.34 per pre-funded warrant share with an exercise price of \$0.01 per share
- **Reflecting a 10% premium** to IMUX’s closing price on October 7, 2022 on NASDAQ

Gross / Net Proceeds

- USD 60.0 million / USD 56.0 million

Participating Investors

- Participation from **new and existing institutional investors**

Closing Date

- October 12, 2022

Lead Placement Agent / Placement Agent

- SVB Securities / Piper Sandler

October: Reported Group-Level Interim Data of Phase 1b Clinical Trial of IMU-935 in Moderate-to-Severe Psoriasis



Identifying Therapeutic Activity of IMU-935 in Moderate-to-Severe Psoriasis Patients

- 28-day double-blind, placebo-controlled dose escalation trial to evaluate safety, tolerability, pharmacodynamics, pharmacokinetics and exploratory efficacy of IMU-935 in patients with moderate-to-severe psoriasis
- Initial two dose cohorts of 150 mg QD and 150 mg BID of IMU-935 did not yet achieve clinical proof-of-concept
 - Group-level interim analysis revealed unexpected high placebo rate; two active arms did not separate from placebo at four weeks
 - Administration of IMU-935 and placebo were safe and well-tolerated, no new safety signals observed
 - Immunic expects to continue IMU-935 development in psoriasis and will determine next steps for the program
 - Immunic plans to provide further updates and guidance on potential next steps towards end of Q1/2023

QD: quaque die = once-daily; BID: bis in die = two times daily

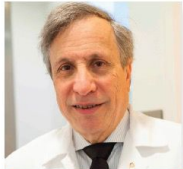
Is Everything Different?

Latest Exciting Scientific Findings and Their Effect on The Multiple Sclerosis Treatment Landscape

AGENDA

11:00 – 11:05: Welcome and Introductions
11:05 – 11:10: Vidofludimus Calcium: Mode of Action
11:10 – 11:30: Vidofludimus Calcium: Phase 2 EMPHASIS Trial in RRMS
11:30 – 12:00: Featured KOL: Fred D. Lublin, MD
12:00 – 12:10: Vidofludimus Calcium: Antiviral Data
12:10 – 12:30: Featured KOL: Lawrence Steinman, MD
12:30 – 13:00: Featured KOL: Heinz Wiendl, MD
13:00 – 13:10: Vidofludimus Calcium: Ongoing ENSURE and CALLIPER Programs
13:10 – 13:20: Vidofludimus Calcium: Strategy and Positioning
13:20 – 13:30: Q&A Session and Closing

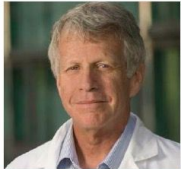
FEATURED KEY OPINION LEADERS



Fred D. Lublin, MD

Saunders Family Professor of Neurology
Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis

Icahn School of Medicine
Mount Sinai Hospital
New York, NY, USA



Lawrence Steinman, MD

Professor of Neurology and Neurological Sciences, Pediatrics, and Genetics
Stanford University School of Medicine

Department of Neurology & Neurological Sciences
Stanford, CA, USA



Heinz Wiendl, MD, PhD

Director Department of Neurology with Institute of Translational Neurology

University of Münster
Münster, Germany



Daniel Vitt, PhD

Chief Executive Officer & President



Hella Kohlhof, PhD

Chief Scientific Officer



Andreas Muehler, MD

Chief Medical Officer

Immunics Multiple Sclerosis R&D Webcast
Thursday, November 17, 2022
11:00am – 1:30pm Eastern Time



November: Hosted Virtual Multiple Sclerosis R&D Webcast



Is Everything Different? Latest Exciting Scientific Findings and Their Effect on the MS Treatment Landscape

- Featured key opinion leaders:
 - Fred D. Lublin, MD, Icahn School of Medicine, Mount Sinai Hospital
 - Lawrence Steinman, MD, Stanford University School of Medicine
 - Heinz Wiendl, MD, PhD, University of Münster, Germany
- Immunics speakers:
 - Daniel Vitt, PhD, CEO & President
 - Hella Kohlhof, PhD, CSO
 - Andreas Muehler, MD, CMO
- Recording: <https://www.youtube.com/watch?v=JAocmnOTQhg>

November: Reported New Data From Phase 2 EMPhASIS Trial in RRMS Supporting Vidofludimus Calcium's Neuroprotective Potential



Data showed encouraging signals for vidofludimus calcium for preventing or delaying confirmed disability worsening



Long-term open-label treatment associated with a low rate of confirmed disability worsening over time



Compares favorably to historical trial data for currently available multiple sclerosis treatments

Treatment of Celiac Disease



Current Pathways for Drug Development & Persistent Disease Activity Despite Gluten-Free Diet as the Unmet Medical Need

AGENDA

11:00 – 11:05: Welcome and Introductions
11:05 – 11:20: Introduction to Celiac Disease
11:20 – 11:30: Celiac Disease Treatment Landscape
11:30 – 11:35: Interleukin-2 Response Following Gluten Ingestion
11:35 – 11:55: Expert Presentation: Joseph A. Murray, MD
11:55 – 12:05: Mechanism of Action and Preclinical Data for IMU-856
12:05 – 12:25: Expert Presentation: Michael Schumann, MD
12:25 – 12:35: Q&A With the Two Experts
12:35 – 12:45: Clinical Overview for IMU-856
12:45 – 13:00: Q&A Session and Closing

FEATURED KEY OPINION LEADERS



Joseph A. Murray, MD

Professor of Medicine
Director, Celiac Disease Research
John and Shirley Berry Professor
of Gastrointestinal Sciences
Division of Gastroenterology
and Hepatology, Department of
Internal Medicine
Mayo Clinic, Rochester, MN



Michael Schumann, MD

Attending Physician in
Internal Medicine and
Gastroenterology
Department of
Gastroenterology, Infectious
Diseases and Rheumatology
Campus Benjamin Franklin
Charité – Universitätsmedizin
Berlin

Register Now

The Celiac Disease R&D webcast will be held virtually via Zoom. To participate, please register in advance at:

https://jimux.zoom.us/webinar/register/WN_wl-01YeSbe4XRTFQ1PLQw

Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

Immunic's Celiac
Disease R&D Webcast
Thursday, February 9, 2023
11:00am - 1:00pm Eastern Time

IMMUNIC SPEAKERS



Daniel Vitt, PhD

Chief Executive
Officer & President



Hella Kohlhof, PhD

Chief Scientific Officer



Andreas Muehler, MD

Chief Medical Officer

February: Hosted Virtual Celiac Disease R&D Webcast



Current Pathways for Drug Development & Persistent Disease Activity Despite Gluten-Free Diet as the Unmet Medical Need

- Featured key opinion leaders:
 - Joseph A. Murray, MD, Mayo Clinic, Rochester, MN
 - Michael Schumann, MD, Charité – Universitätsmedizin Berlin
- Immunic speakers:
 - Daniel Vitt, PhD, CEO & President
 - Hella Kohlhof, PhD, CSO
 - Andreas Muehler, MD, CMO
- Recording: <https://www.youtube.com/watch?v=xsPJQHpw-BI>

February: Announced Presentation of Data From Phase 2 EMPHASIS Trial at ACTRIMS Forum 2023

Assessment of effect of vidofludimus calcium on confirmed disability worsening in the blinded treatment and open-label extension periods of the phase 2 study (EMPhASIS) in relapsing-remitting multiple sclerosis

The eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis Forum 2023



R. Fox
Cleveland Clinic,
Cleveland, OH, USA

C. Wolf
Lycells,
Brussels, Belgium

V. Sciacca
Immunic AG,
Gräfelfing, Germany

M. Ondrus
Immunic AG,
Gräfelfing, Germany

A. Muehler
Immunic AG,
Gräfelfing, Germany

Background

Vidofludimus calcium (VidoCa) is a highly selective oral 2nd generation DHODH inhibitor, which in the double-blind phase 2 EMPHASIS trial in relapsing-remitting multiple sclerosis (RRMS) has shown a robust activity against placebo and a safety and tolerability profile comparable to placebo, presumably due to lack of off-target effects on kinases. This summary describes the first interim analysis of the ongoing long-term open-label extension period focusing on disability worsening during the continued treatment with VidoCa in RRMS patients.

Objective

EMPhASIS was a randomized, placebo-controlled phase 2 trial in RRMS, assessing efficacy and safety of 10, 30 and 45mg of VidoCa as compared to placebo for a period of 24-weeks. Upon completion of the double-blind treatment period, the study participants could enter the long-term open-label extension (OLE) period with further monitoring of safety, tolerability, and selected efficacy parameters (such as EDSS). Herein we report the long-term activity of VidoCa on confirmed disability worsening events in RRMS patients.

Methods

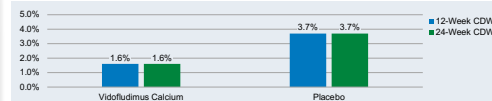
In the EMPHASIS trial, 268 patients with RRMS received study medication with either 10, 30, or 45 mg VidoCa or placebo for a double-blind treatment of 24 weeks. Upon completion of the double-blind period, 254 patients continued in the OLE period. The patients originally randomized to VidoCa 30 and 45 mg continued with the same dose, while the patients originally assigned to placebo or VidoCa 10mg were randomly assigned to either 30 or 45mg of VidoCa. The original treatment allocation was disclosed only after the last patient completed the main treatment period. Subsequently, a transition of all patients in OLE period to 30 mg VidoCa was initiated.

Results

- As of October 2022, 209 patients remained on OLE treatment with VidoCa, with some patients having received more than 180 weeks of active treatment (roughly 3.5 years).
- For the initial 24-week double-blind treatment period, 12-week Confirmed Disability Worsening (12wCDW) and 24-week Confirmed Disability Worsening (24wCDW) events occurred in 1.6% of subjects in the combined VidoCa treatments arms as compared to 3.7% in the placebo group.
- In the OLE period, the proportion of patients free from 12wCDW was 97.2% after 48 weeks and 94.2% after 96 weeks of VidoCa treatment. Similar results were seen for 24wCDW and sustained CDW (i.e. CDW persisting through last assessment).
- Among VidoCa patients in the OLE period of the trial, 3% experienced one or more relapses within the first year and 6.2% within the first two years.

Confirmed Disability Worsening Events

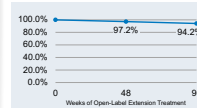
End during the initial 24-week blinded treatment period



Data suggest a possible benefit of VidoCa on 12-week and 24-week confirmed disability worsening¹ events as compared to placebo. Confirmatory data will be obtained in the ongoing phase 3 ENSURE clinical program.

Interim analysis regarding 12wCDW events

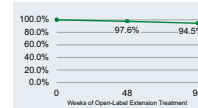
Patients free of 12-week CDW after 1 & 2 years of OLE VidoCa Treatment



Data show that only a few patients on continuous treatment with VidoCa develop 12-week CDW events over 2 years.

Interim analysis regarding 24wCDW events

Patients free of 24-week CDW after 1 & 2 years of OLE VidoCa Treatment



Data show that only a few patients on continuous treatment with VidoCa develop 24-week CDW events over 2 years.

Conclusion

Over the 24 weeks of blinded treatment and the open-label extension period, rates of CDW in VidoCa-treated patients were low. These findings provide an initial signal for VidoCa preventing or slowing confirmed disability progression in RRMS.

CDW: confirmed disability worsening; EDSS: Expanded Disability Status Scale

¹Only disability worsening with a trigger point during the 24-week blinded treatment period are considered. The EDSS increases during the blinded treatment phase were subsequently confirmed during open-label extension phase of the trial. Patients at risk in this analysis are 187 for vidofludimus calcium (pooling 10, 30 and 45 mg data) and 81 for placebo. The trigger event is an EDSS progression defined as an increase in the EDSS compared to baseline of at least 1.5 points if Baseline EDSS = 0, of at least 1.0 points if Baseline EDSS = 1-4, or of at least 0.5 points if Baseline EDSS = 5-5.5. 12-week CDW: The confirmation event is at least 77 days after the trigger event. At the confirmation event and each assessment between trigger and possible confirmation event, EDSS must be at least as high as at the trigger event. 24-week CDW is defined analogously, the only difference being the time interval between trigger event and confirmation visit, which is at least 161 days. Full analyses set posted cohorts: 1&2 (N10 = 47, N30 = 71, N45 = 66, NPOD C1 = 66, NPOD C2 = 12)



- Eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2023
- February 23-25 in San Diego, California
- Poster Presentation: Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio
- Data from the blinded and open-label extension parts of Immunic's phase 2 EMPHASIS trial of vidofludimus calcium in RRMS



02

Financial and Operating Results

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts, unaudited)

	Years Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 71,255	\$ 61,115
General and administrative	15,263	13,300
Goodwill impairment	32,970	—
4SC Royalty Settlement	—	17,250
Total operating expenses	119,488	91,665
Loss from operations	(119,488)	(91,665)
Other income (expense):		
Interest income	1,041	66
Other expense, net	(1,960)	(1,346)
Total other expense	(919)	(1,280)
Net loss	\$ (120,407)	\$ (92,945)
Net loss per share, basic and diluted	\$ (3.78)	\$ (3.93)
Weighted-average common shares outstanding, basic and diluted	31,819,006	23,652,779

→ \$116.4 million in cash, cash equivalents and investments as of December 31, 2022 are expected to fund operations into the fourth quarter of 2024



03

Anticipated Clinical Milestones

Vidofludimus Calcium in Multiple Sclerosis

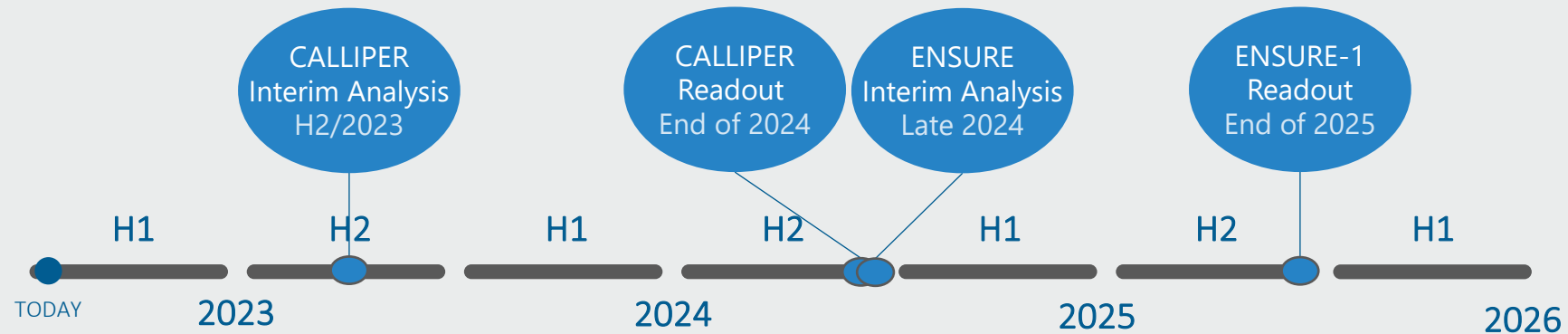
Straightforward Approval Strategy

Phase 3 ENSURE Program in RMS^[1]

- Two identical pivotal trials in RMS patients
- Goal: Low risk clinical program for regulatory approval of vidofludimus calcium
- Dosage: 30 mg vidofludimus calcium QD

Phase 2 CALLIPER Trial in PMS^[2]

- Phase 2 trial in PMS patients
- Goal: Demonstrate vidofludimus calcium's potential for neuroprotective activity in a non-relapse setting
- Dosage: 45 mg vidofludimus calcium QD



[1] ClinicalTrials.gov: NCT05134441 & NCT05201638; [2] ClinicalTrials.gov: NCT05054140
RMS: relapsing multiple sclerosis; PMS: progressive multiple sclerosis; QD: quaque die = once-daily

IMU-935 Phase 1 Clinical Trial in Psoriasis



Immunic expects to provide further updates and guidance on potential next steps for the phase 1 clinical trial of IMU-935 in moderate-to-severe psoriasis towards the end of Q1/2023.

IMU-856 Phase 1 Clinical Trial in Celiac Disease



Initial data from the ongoing Part C of the phase 1 clinical trial of IMU-856 in celiac disease patients is expected to be available in mid-2023.



04

Q&A Session



05

Summary and Highlights

Advanced Clinical Pipeline

Three Differentiated Programs in Various Phases of Clinical Development

Program	Target	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones
Vidofludimus Calcium (IMU-838)	DHODH					<ul style="list-style-type: none">Initial phase 1b celiac disease data of IMU-856 expected in mid-2023Interim analysis of CALLIPER trial in PMS planned after half of the patients completed 24 weeks of treatment, estimated for H2/2023
		Relapsing Multiple Sclerosis (RMS) – ENSURE Trials				
		Progressive Multiple Sclerosis (PMS) – CALLIPER Trial				
Izumerogant (IMU-935)	IL-17 / RORγt					<ul style="list-style-type: none">Interim analysis of first ENSURE trial in RMS planned after approximately half of the events occurred, estimated for late 2024CALLIPER trial estimated to readout end of 2024ENSURE-1 trial estimated to readout end of 2025, ENSURE-2 soon thereafter
		Psoriasis				
		Castration-Resistant Prostate Cancer (CRPC)				
IMU-856	Intestinal Barrier Function		Celiac Disease			

Thank You!



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