



**BERENBERG AND GOLDMAN
SACHS FIFTH GERMAN
CORPORATE CONFERENCE**

DR. MARIOLA SOEHNGEN - CEO

MUNICH, 21 SEPTEMBER 2016

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MOLOGEN Snapshot

MOLOGEN AG
THE POWER OF IMMUNOTHERAPIES

- Based in Berlin, Germany; founded 1998
- ~ 65 employees
- One of the pioneers in immunotherapies
- Focus on family of TLR9 agonists:
 - Lefitolimod (MGN1703)
 - Next generation technology EnanDIM®
- Highly attractive markets: A multi-billion US market



- Close network with scientific institutions & experts

THE UNIVERSITY OF TEXAS
MDAnderson
Cancer Center

Aarhus University Hospital

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

Freie Universität  Berlin

MDC MAX DELBRÜCK CENTER
FOR MOLECULAR MEDICINE
BERLIN-BUCH

Dr. Mariola Soehngen, CEO (since Nov 2015)

- Extensive expertise & experience in the biotechnological and pharmaceutical industry
- Co-founder of the German biotechnology company PAION AG
- Responsible for Strategy, Partnering, Business Development as well as Research, Production, Investor Relations and Corporate Communications

Walter Miller, CFO (since Apr 2016)

- Extensive expertise in the biotechnological and pharmaceutical industry; long standing experience in Finance & Management
- Management functions in both startups and listed Biotech-companies (e.g. Santhera Pharmaceuticals Group, Nuvisan GmbH)
- Responsible for Finance and Administration, Human Resources, Risk Management, Compliance and Corp. Governance as well as Legal and IT

Achievements 2015 until today

Portfolio-Review: Basis for new strategy “Next Level”



IMPALA pivotal trial: Patient recruitment well advanced



Randomized study IMPULSE (SCLC) – Finalized patient recruitment



Started combination study with MD Anderson Cancer Center, US: Lefitolimod + ipilimumab (Yervoy®)



TEACH: Cooperation with University of Aarhus, completion of first phase of TEACH trial in HIV




Continued partnering discussions



Successful capital increase in April 2015



New strategy „Next Level“ – Initial situation: Research-driven company

- Before „Next Level“ strong focus on basic research; only inhouse production
 - Broad pipeline portfolio based on three different proprietary platforms
 - Basic research was to support mainly existing projects only
 - So far, internal production was limited to cover medication for the clinical trials (small scale); medication requirements fully stocked until end of clinical trials
 - Production on a large scale can only be achieved by outsourcing to external partners
 - Prerequisite to attain potential license partners
- 
- Outsourcing of basic research & production: best way forward
 - Outsource production: time-consuming; start now

Current and target portfolio - Focus on lefitolimod & EnanDIM®

DNA-based TLR9 agonists (ISRs)

- Bind to TLR9 receptors
- Several Immune Surveillance Reactivators (ISR) in development:
 - Lefitolimod (MGN1703): Four ongoing trials
 - EnanDIM®: New class of linear TLR9 agonists
- Suitable for mono- and combination therapies

Focus

MIDGE® Vector System

- DNA-based, non-viral vector system: gene ferries
- Three products in development:
 - MGN1404 (malignant melanoma), phase I
 - MGN1331 (leishmaniasis)
 - MGN1333 (hepatitis B)

Divestment/Spin-off

Cell-based therapeutic vaccination (MGN1601)

- Genetically modified unique human renal cancer cell line using MIDGE® platform – combined with low-dose lefitolimod as adjuvant
- Phase I/II data available
- Orphan drug status

Backup

New strategy „Next Level“ – Shift to market-oriented company and life cycle management

- Strong market- and product-oriented strategy program
- Focus on close-to-market compounds and successor molecules:
 - Lead product immunomodulator lefitolimod (MGN1703)
 - EnanDIM[®]: Lefitolimod successor molecules; next-generation technology
- MGN1601: Shelve clinical development – backup compound
- MIDGE[®] technology: Divestment or spin-off
- Streamline company’s organizational structure
- Accelerate commercialization of products via out-licensing
 - Variability of costs and increased flexibility
 - No substantial impact on guidance for FY 2016
 - Complete reorganization by the end of 2016
 - Create added value



Target portfolio - Focus on lefitolimod & EnanDIM®

Platform	Compound	Indications	PC	PH I	PH II	PH III	Study	Cooperation partners
DNA-based TLR9 agonists (ISR)	Lefitolimod (MGN1703)	• Metastatic colorectal cancer (mCRC)	████████████████████				IMPALA	-
		• Small cell lung cancer (SCLC)	████████████████				IMPULSE	-
		• HIV	██████████				TEACH	Aarhus University Hospital
		• Advanced solid malignancies	██████████				Lefitolimod & ipilimumab	MD Anderson Cancer Center
	EnanDIM®	• Cancer / anti-infective therapies	██					
Therapeutic Vaccine (cell-line)	MGN 1601	• Renal cancer	██████████				On hold: backup compound	

Lefitolimod (MGN1703) – Ongoing clinical trials

IMPALA	IMPULSE	TEACH	Combination trial
Metastatic Colorectal Cancer (mCRC)	Small Cell Lung Cancer (SCLC)	HIV (Infectious Disease)	Advanced Solid Malignancies
<ul style="list-style-type: none"> • Pivotal trial (phase III) • 540 patients • 8 European countries: Austria, Belgium, Estonia, France, Germany, Italy, Spain, UK <p>→ Recruiting ongoing</p>	<ul style="list-style-type: none"> • Randomized study • 100 patients • 4 European countries: Austria, Belgium, Germany, Spain <p>→ Recruitment completed (Oct 2015)</p>	<ul style="list-style-type: none"> • Phase I • 15 patients (first phase); 15 patients in extension phase • “kick and kill“ concept of HIV eradications • Denmark <p>→ Extension phase: FPI (Jun 2016)</p>	<ul style="list-style-type: none"> • Lefitolimod (MGN1703) + ipilimumab (Yervoy®) • Phase I • 50-60 patients • Texas, US <p>→ Study started (Jul 2016)</p>

Lefitolimod (MGN1703) – Milestones clinical trials

	IMPALA (mCRC) – Pivotal study	IMPULSE (SCLC) – Randomized study	TEACH (HIV) – Phase I	Combination trial – Phase I
2014	First patient in (FPI) ✓	First patient in (FPI) ✓		
2015		Recruitment completed ✓	Start/end of first phase ✓	
2016	Recruitment completed	Start of primary analyses (OS)	Initial results of first phase; start extension ✓	First patient in (FPI) ✓
2017		Final results	Final results	End of recruitment
2018	Start primary endpoint analysis (OS)			
2019	Results			Start of primary analyses

Strategic focus

Partnering agreement for
lefitolimod (MGN1703)

High returns in the mid- and long-term

Prepare potential market entry
for lefitolimod

Increasing value of product family

Shelve clinical development
of MGN1601

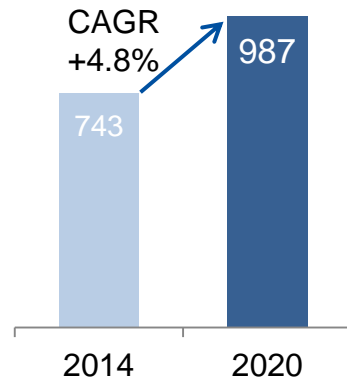
Backup compound

Initiate new opportunities with
lefitolimod

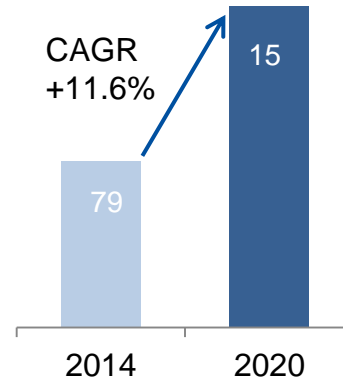
Initiate combi trials; extend and advance
product pipeline: ensure long-term growth

Oncology market - Sales by leading therapy category

Worldwide Prescription Drugs¹



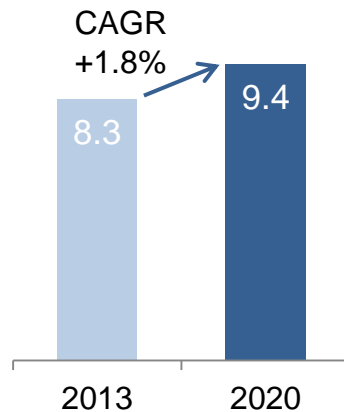
Worldwide Oncology Drugs¹



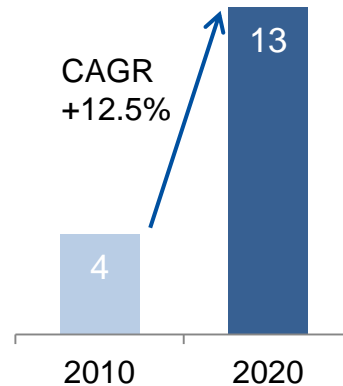
Sales in US\$ bn

- Oncology is expected to be one of the therapeutic areas with highest growth rates & strongest sales worldwide
- Cancer immunotherapies represent huge market potential: ~US\$ 35 bn

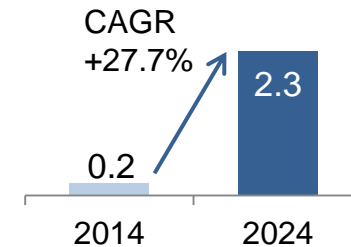
Colorectal Cancer²



Lung Cancer³

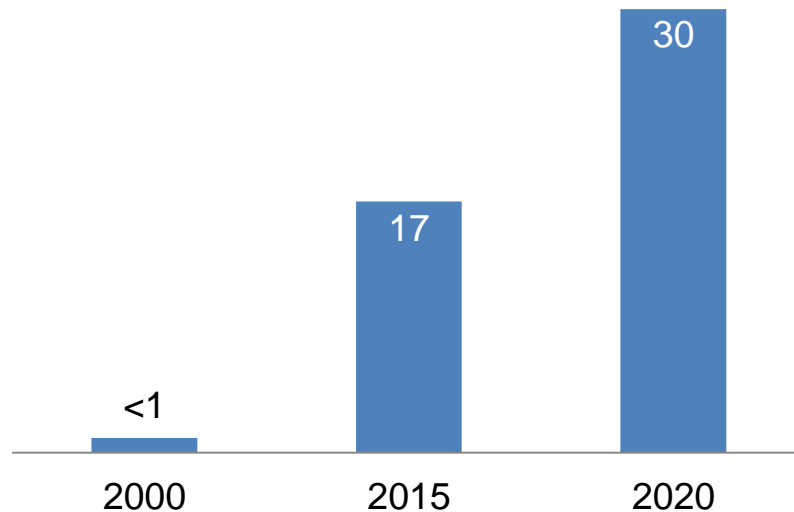


SCLC⁴



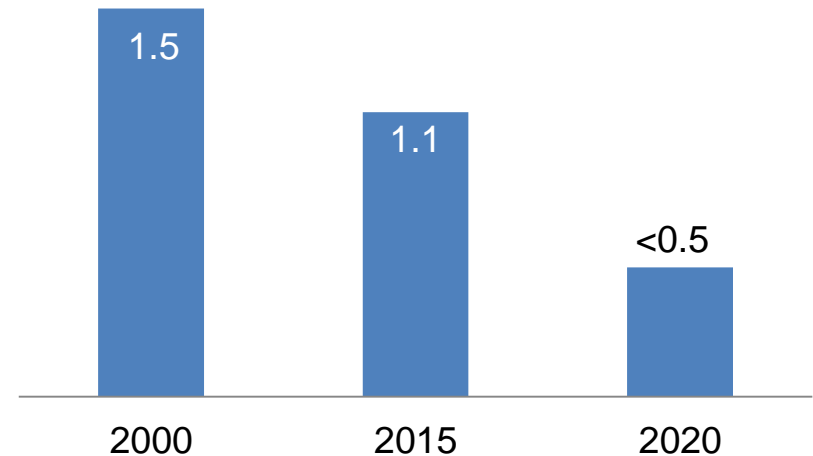
HIV market – Decreasing death rates

People living with HIV on ART (in million)



- Better diagnostics and price reductions of medicines

AIDS-related deaths



- Improved treatment regimens and diagnostics

Combination therapies - The next opportunity

- Combination therapies have increased and are expected to be launched in increased numbers in the coming years
- Treatment options will increase with launch of new immunotherapeutic agents
- Combinations of immunotherapies with any other therapies will play integrative role in future new immunotherapy approaches or breakthrough outcomes



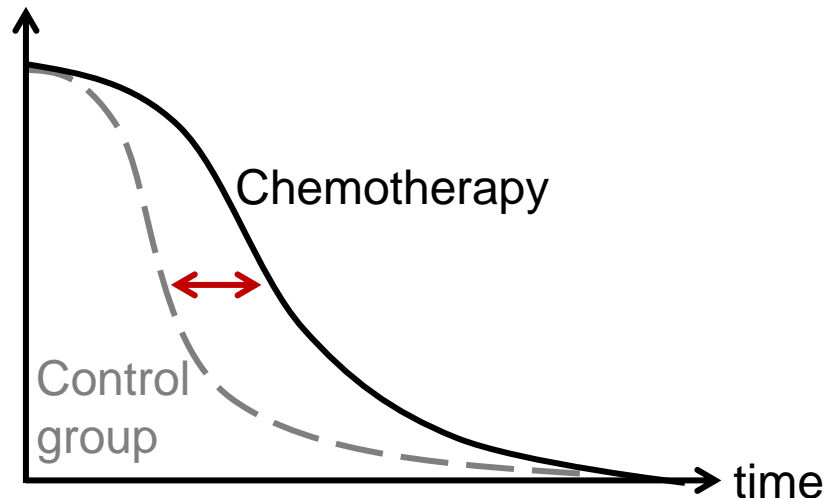
New partnering opportunities

Cancer immunotherapy - How to increase Overall Survival?

Chemotherapy

- Fast effect in many patients
- Effect not lasting

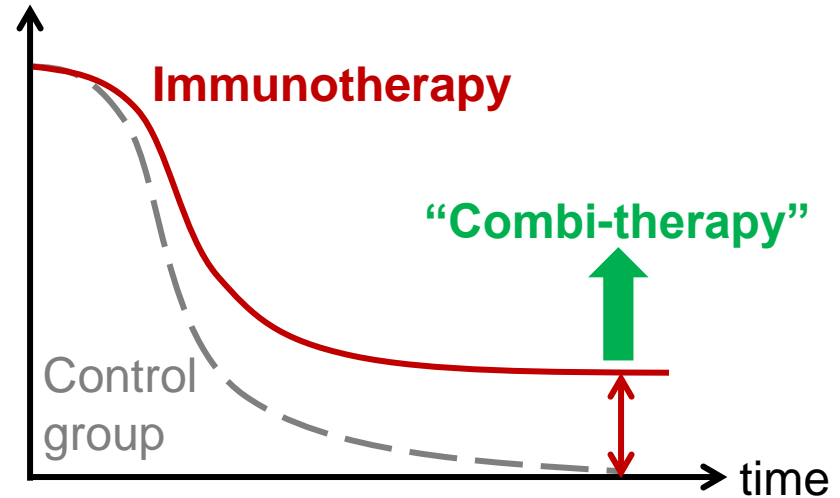
Patients
alive in %



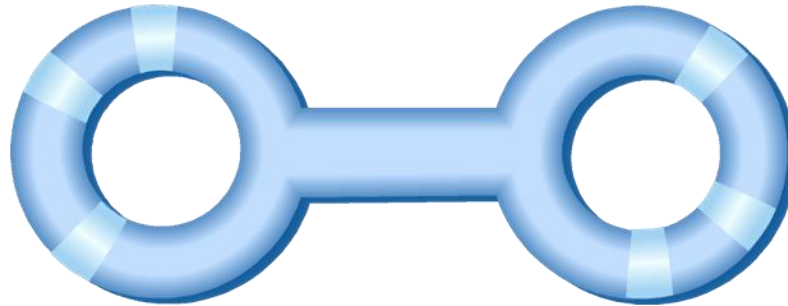
Immunotherapy

- Needs time to be effective
- Long-lasting effect in a subgroup of patients

Patients
alive in %



Lefitolimod (MGN1703) - „Best in class“ TLR9 agonist

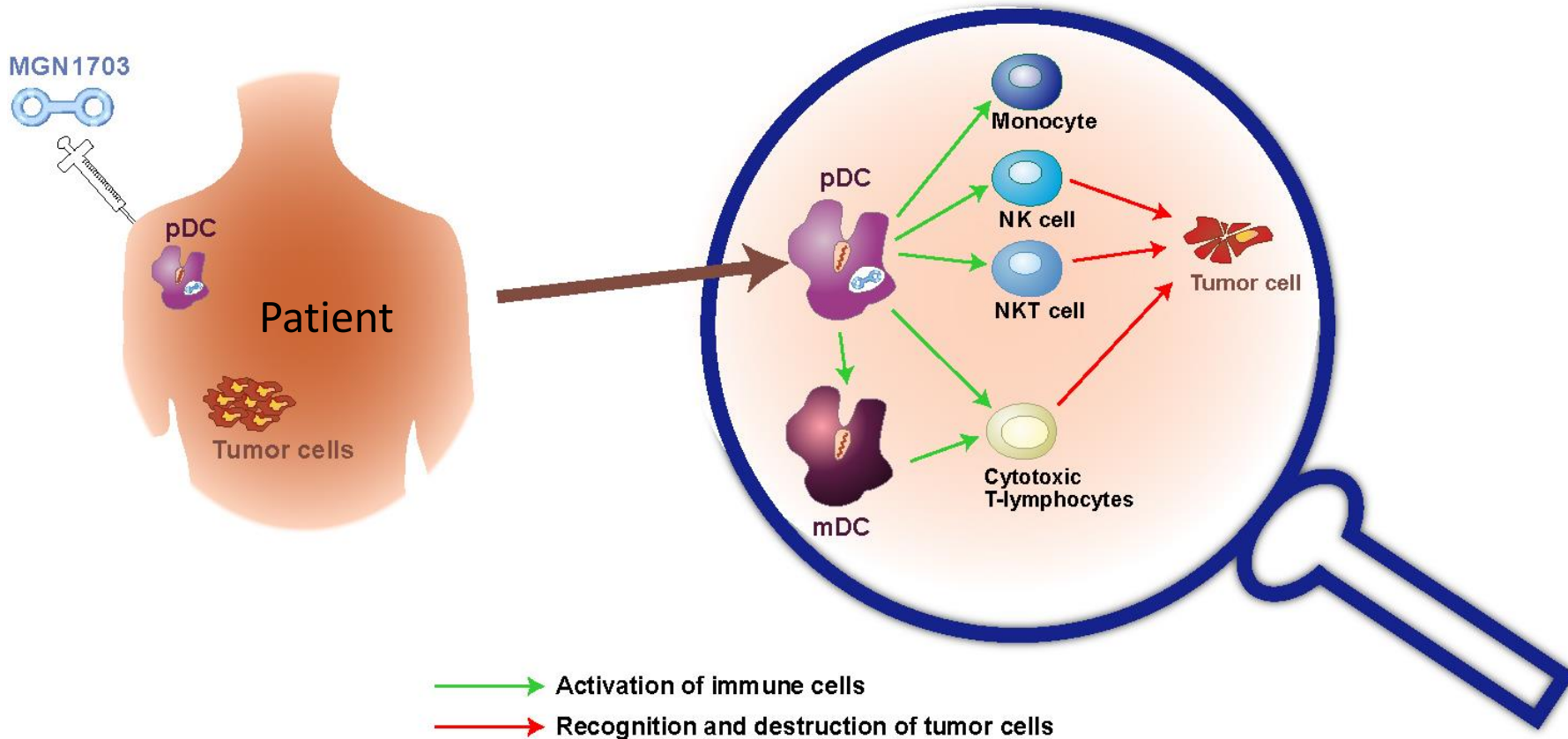


- Immunologic activation and good safety profile due to molecular structure
- High dosing over long periods of time without major toxic effects
- Clinical strategy optimized for lefitolimod (MGN1703) TLR9 activation pattern


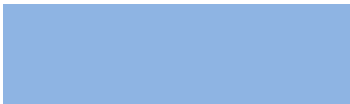






Maximized probability of success compared to other TLR9 agonists

Lefitolimod (MGN1703) - Activating the immune system



Lefitolimod (MGN1703), EnanDIM[®] and MGN1601 – Status exclusivity

Indications	PC	PH I	PH II	PH III	Exclusivity at least until
• Metastatic colorectal cancer (mCRC)					EU: 2030 USA: 2028
• Small cell lung cancer (SCLC)					EU: 2030 USA: 2028
• HIV					EU: 2036 USA: 2036
• Checkpoint Inhibitor Combination					EU: 2036 USA: 2036
• EnanDIM [®]					EU: 2035 ¹ USA: 2035 ¹
• Cell-based therapeutic vaccine (MGN1601)					EU: 2036 USA: 2038

Conclusion: Lefitolimod (MGN1703) – Unique profile and huge market potential

Best in class TLR9 agonist and most advanced in mCRC (pivotal trial)

Usable for various indications (mCRC, SCLC,...)

Superior safety and tolerability: No chemical modification; long treatm. possible

Suitable for mono- and combination therapy



Blockbuster potential

EnanDIM® -

Next generation TLR9 agonists

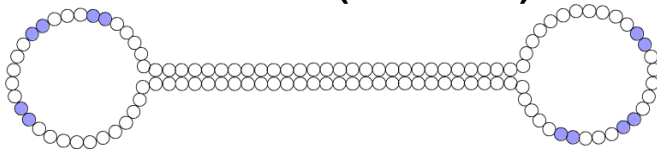
- New class of linear TLR9 agonists
 - Specific structure protects against degradation – no chemical modifications needed
 - Combines advantages of molecules containing only natural DNA components (safety) with benefits from linear molecules (simple production process)
- Broad immune activation and anti-tumor effect shown in pre-clinical models
- Potential application in the fields of cancer and anti-infective therapies



Bring EnanDIM® into clinical development as part of life cycle management - In line with new strategy “Next level”

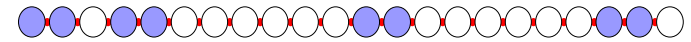
Combining advantages of two types of agonists

Lefitolimod (MGN1703)



- Closed, dumbbell-shaped structure
- Only natural DNA components
- Good safety and tolerability profile
- One additional production step

Linear DNA-structure



- Linear molecules
- Easy and cost-effective production
- Chemically modified structure (usually leads to low risk/benefit ratio)



EnanDIM[®] = Enantiomeric DNA-based ImmunoModulator



- Linear molecules
- No chemical modifications
- Good safety and tolerability profile expected
- Easy and cost-effective production



DNA sequence essential for function (so-called "CG motifs")



New structural feature Protection against degradation

Key financials H1 2016 and FY 2015

In € million	H1 2016	H1 2015	Δ	FY 2015
R&D expenses	7.1	5.2	37%	16.8
EBIT	-9.8	-6.9	42%	-20.5
Cash flows from operating activities	-9.2	-4.7	96%	-15.1
Cash flows from financing activities	0	26.1	-100%	26.2
Monthly cash burn	1.5	1.2	25%	1.4

In € million	30 Jun 2016	31 Dec 2015	Δ	31 Dec 2015
Total assets	16.5	26.4	-37%	26.4
Cash & cash equivalents	15.3	24.6	-38%	24.6
Equity ratio	59%	74%	-20%	74%

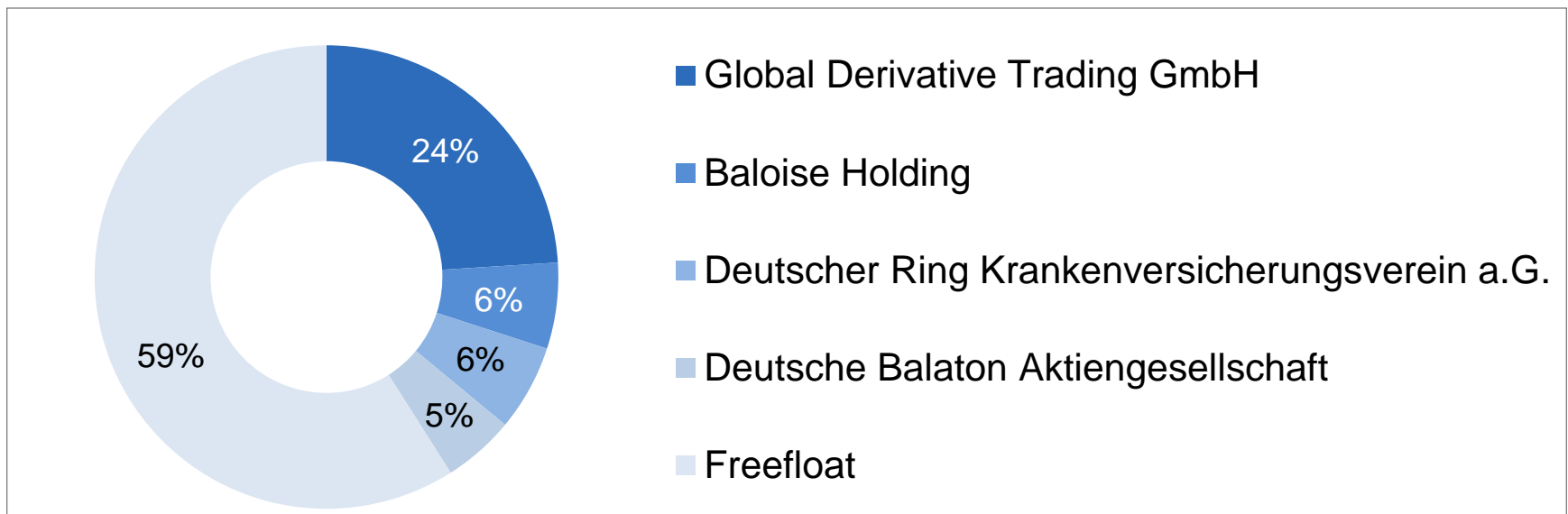
- Main items impacted by study progress: R&D, cash outflows



- Outlook 2016 confirmed
- Next level strategy including upscaling: Mid- and long-term increase of R&D expenses

Shares

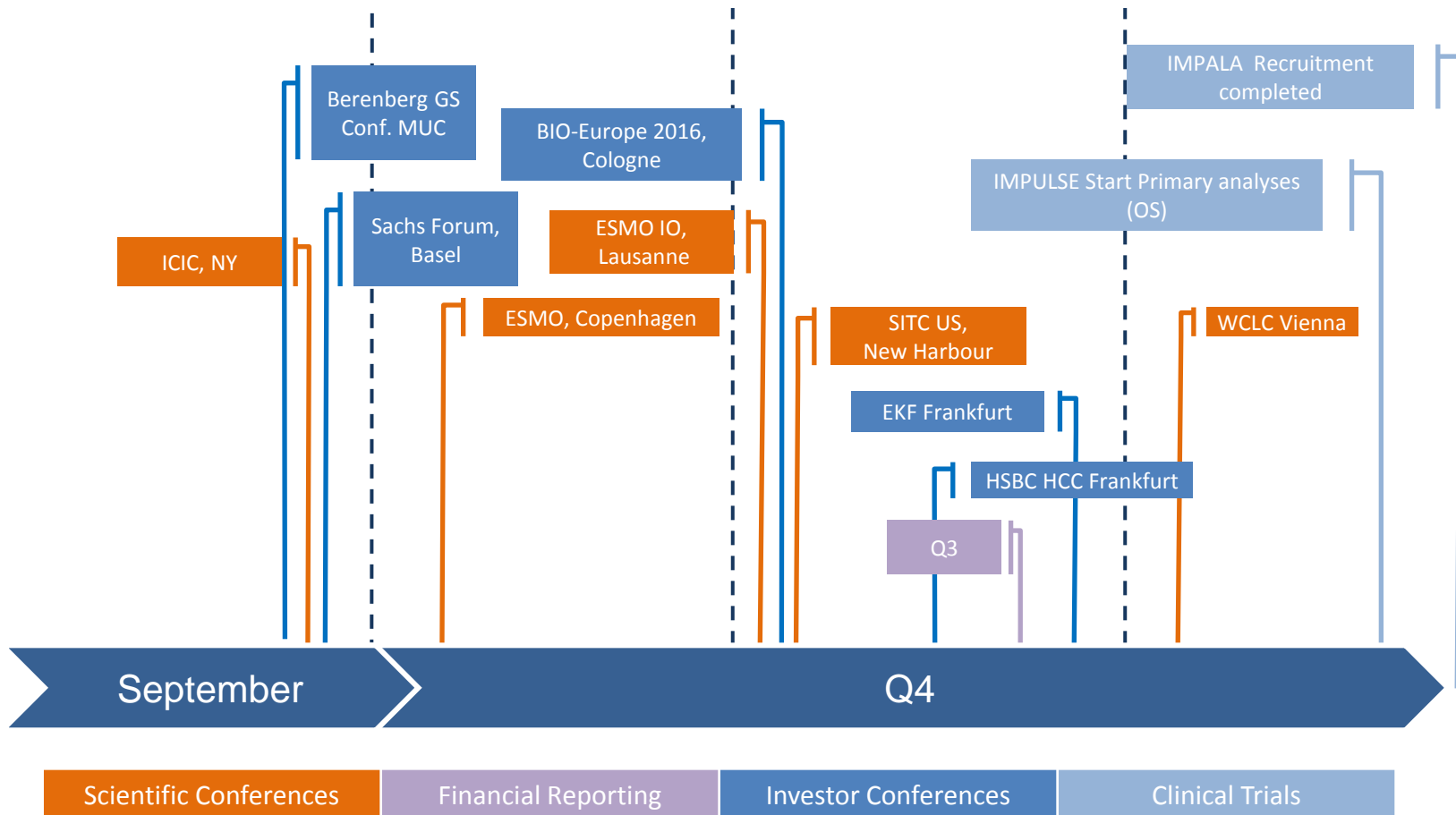
- ISIN DE0006637200
- Shares issued: 22,631,501
- Market capitalization ~ €40m (September 2016)
- Frankfurt Stock Exchange (Prime Standard): MGN I Reuters: MGN.DE



Investment case: Enable execution of strategy “Next level”

- Focus on main product lefitolimod (MGN1703): Best in-class TLR9 agonist with huge market potential – Blockbuster
- Attractive for partnering: Close to market compound with long-term exclusivity; promising next generation successor molecules
 - Next inflection points will be achieved:
 - Finalization of patient recruitment IMPALA
 - Results IMPULSE and TEACH

Upcoming events 2016



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