

# H1 2023 financial results

*04 Aug 2023*

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**Galápagos**

# Disclaimer

This presentation contains “forward-looking statements”, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as “vision”, “progress”, “accelerate”, “believe”, “anticipate”, “plan”, “continue”, “forward”, “goal”, “should”, “expect”, “deliver”, “further”, “estimate”, “next”, “encouraging”, “aim”, “potential”, “will”, and “initiate”, as well as any similar expressions. Forward-looking statements contained herein include, but are not limited to, the guidance from management regarding our financial results, including our expected operational use of cash during financial year 2023 and the adjusted net sales guidance for Jyseleca® during financial year 2023, statements regarding our strategy and plans, including our strategic and capital allocation priorities, statements and analyses related to our CAR-T delivery model and related therapeutics, statements regarding preliminary, interim and topline data from our studies, including, but not limited to, the EUPLAGIA-1, ATALANTA-1, GALARISSO, and GALACELA studies and any other analyses related to our portfolio, statements regarding the expected timing, design and readouts of our ongoing and planned preclinical studies and clinical trials, including the recruitment for such studies and trials, and our plans and strategy with respect to the such studies and trials, statements regarding the timing and likelihood of business development projects and external innovation, statements regarding our strategic transformation, statements regarding our regulatory outlook, statements regarding our R&D plans, strategy and outlook, including progress on our immunology or oncology portfolio, and CAR-T-portfolio, and any potential changes in such strategy, statements regarding our pipeline and complementary technology platforms facilitating future growth, statements regarding our expectations on commercial sales of filgotinib and any of our other product candidates (if approved), statements regarding the transfer of our drug and research activities and employees exclusively dedicated to the activities in Romainville (France), statements regarding the five year-collaboration between Galapagos and NovAliX, statements regarding our collaboration with Lonza, statements regarding the global R&D collaboration with Gilead for the commercialization and development of filgotinib, as amended, statements regarding the amount and timing of potential future milestones and other payments, statements relating to interactions with regulatory authorities, statements regarding the changes in our leadership and expected resulting benefits, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements regarding our commercialization efforts for filgotinib, our product candidates, and any of our future approved products, statements relating to the development of our commercial organization, statements and expectations regarding the rollout of our products or product candidates (if approved), and statements related to the expected reimbursements for Jyseleca®, statements regarding the timing, design and readouts of ongoing and planned preclinical studies and clinical trials, including statements regarding our plans and strategy related to the development of our CD19 CAR-T candidates, GLPG5101 and GLPG5201, including patient enrollment for the Phase 1/2 ATALANTA-1 study and the EUPLAGIA-1 study, and the timing for topline results from such studies, statements regarding the timing for initiation of the Phase 1/2 PAPILIO-1 study with BCMA CAR-T product candidate, GLPG5301, and statements regarding our strategy, business plans and focus.

We caution the reader that forward-looking statements are based on our management’s current beliefs and expectations and are not guarantees of future performance. Forward-looking statements may involve any known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements, or the industry in which we operate, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such statements. Such risks include, but are not limited to, the risk that our beliefs, guidance, and expectations regarding our 2023 revenues, operating expenses, cash burn, net sales, and other financial results may be incorrect (including because one or more of its assumptions underlying our revenue, expense, cash burn, sales or result expectations may not be realized), the risk that ongoing and future clinical trials may not be completed in the currently envisaged timelines or at all, risks related to the transfer of the drug discoveries and research activities conducted in Romainville (France) and employees exclusively dedicated to these activities to NovAliX, the inherent risks and uncertainties associated with competitive developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including the risk that data from our ongoing and planned clinical research programs in RA, UC, AxSpA, SLE, DM, NHL, CLL, MM, or any other indications or diseases, may not support registration or further development of its product candidates due to safety or efficacy concerns or any other reasons), the inherent risks and uncertainties associated with target discovery and validation, and drug discovery and development activities, the risk that the initial and topline data from our trials and studies, including, but not limited to, the ATALANTA-1, EUPLAGIA-1, GALARISSO and GALACELA studies, may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including, but not limited to, Gilead and Lonza), the risk that the transition of the European commercialization responsibility of filgotinib from Gilead to us, will not have the currently expected results for our business and results of operations, the risk that estimates regarding our filgotinib development program and the commercial potential of our product candidates and our expectations regarding the revenues and costs associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, including the risk that our plans with respect to CAR-T may not be achieved on the currently anticipated timeline or at all, the risk that our projections and expectations regarding the commercial potential of our product candidates or expectations regarding the costs and revenues associated with the commercialization rights may be inaccurate, the risks related to our strategic transformation, including the risk that we may not achieve the anticipated benefits of such transformation on the currently envisaged timeline or not at all, the risk that we will encounter challenges retaining or attracting talent, risks related to disruption in our operations, supply chain or ongoing studies due to the conflict between Russia and Ukraine, risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including the EC and EMA, and the EMA’s safety review of JAK inhibitors used to treat certain inflammatory disorders, the risk that the EMA and/or other regulatory authorities may determine that additional post-approval trials of filgotinib or any other product candidates that are approved in the future would be required, the risk that the EMA and/or other regulatory authorities may require that the market authorization for filgotinib in the EU be amended, the risk that the EMA and/or other regulatory authorities may impose JAK class-based warnings, and the risk that the EMA’s safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors, and the risks and uncertainties related to the impact of the COVID-19 pandemic. A further list and description of these risks, uncertainties and other risks can be found in our filings and reports with the Securities and Exchange Commission (“SEC”), including in our most recent annual report on Form 20-F filed with the SEC, and our subsequent filings and reports filed with the SEC. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if the result of our results, performance, financial condition and liquidity, or the industry in which we operate, are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation to update any such statements herein to reflect any change in our expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

Except for filgotinib’s approval as Jyseleca® for the treatment of RA and UC by the European Commission, Great Britain’s Medicines and Healthcare Products Regulatory Agency, and the Japanese Ministry of Health, Labour and Welfare, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

Under no circumstances may any copy of this presentation, if obtained, be retained, copied or transmitted.

# Agenda

- 1 Introduction and R&D update Dr. Paul Stoffels\*, CEO
- 2 Operational & financial update Thad Huston, CFO & COO
- 3 Q&A All

# Agenda

- |   |                                |                        |
|---|--------------------------------|------------------------|
| 1 | Introduction and R&D update    | Dr. Paul Stoffels, CEO |
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| 3 | Q&A                            | All                    |

# Thad Huston, CFO & COO



- Seasoned healthcare executive
- Global financial, commercial, BD & operational experience
- Senior VP, Finance & Corporate Operations at Kite Pharma  
CFO LivaNova Plc  
Leadership positions at JNJ for >25 years

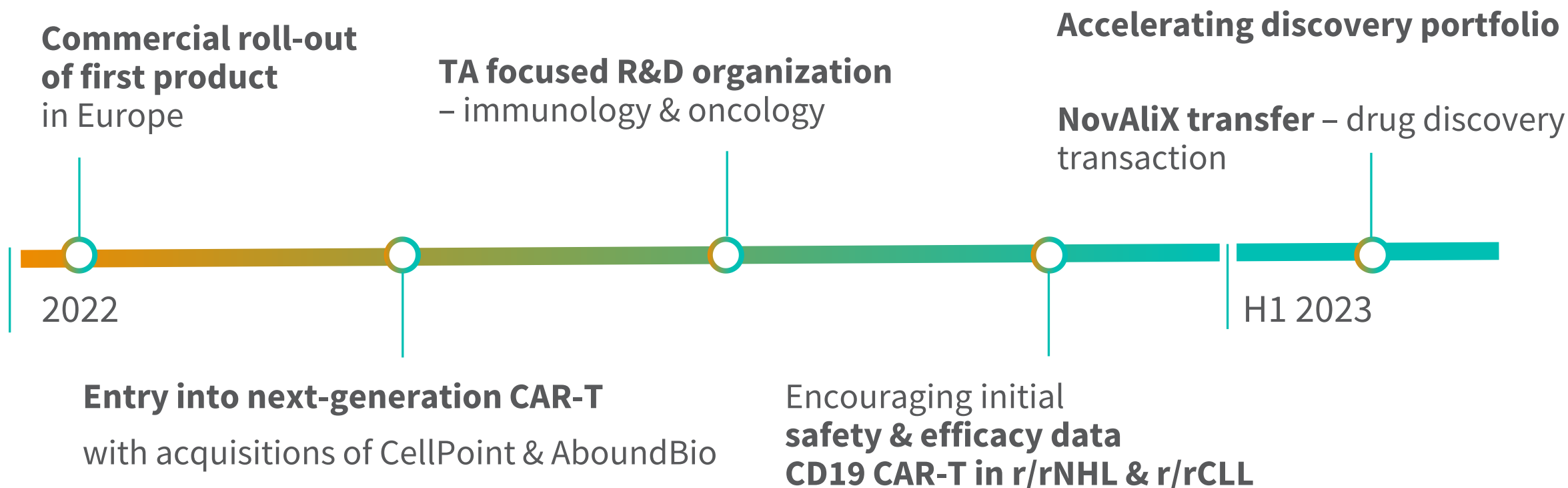
## OUR VISION

Galapagos' vision is to **transform patient outcomes** through **life-changing science** and **innovation** for more **years** of life and **quality** of life.

## OUR MISSION

We **accelerate** transformational **innovation** through the relentless pursuit of **groundbreaking science**, our **entrepreneurial** spirit and a **collaborative** mindset.

# Executing on transformation to unlock value





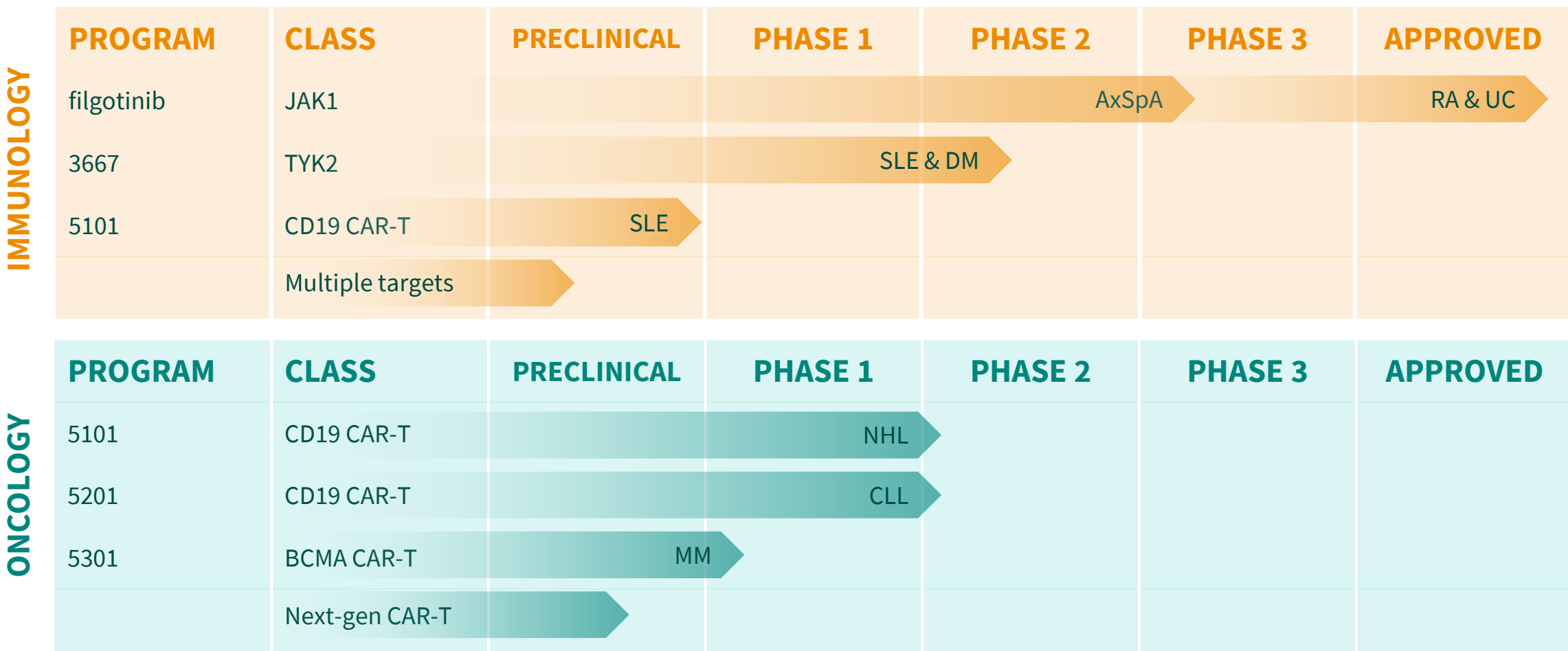


# Clinical update



# Accelerating our pipeline

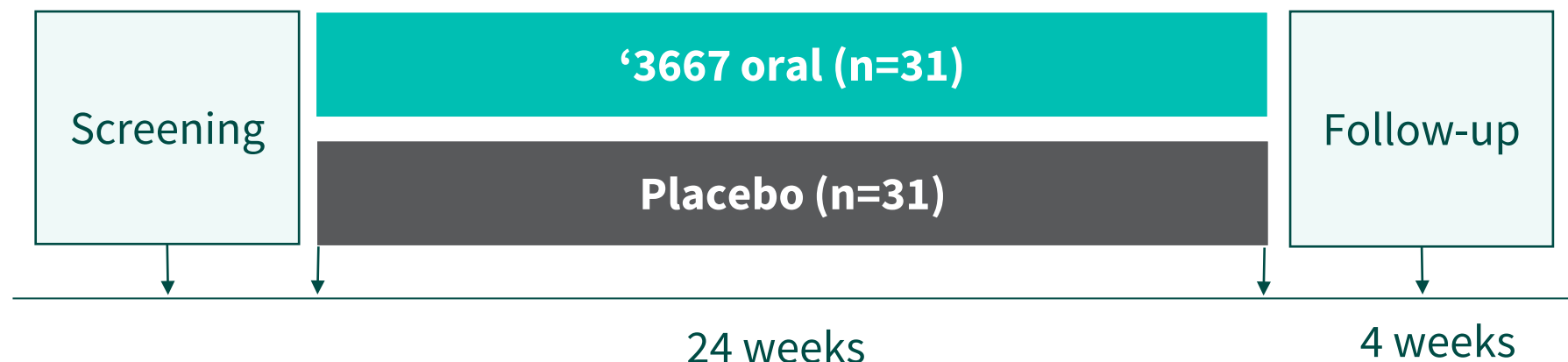
## Our portfolio from discovery to patients



Filgotinib is approved for RA and UC in EU, Great Britain and Japan  
 AxSpA, axial spondyloarthritis; CLL, chronic lymphocytic leukemia; DM, dermatomyositis; MM, multiple myeloma; NHL, non-Hodgkin lymphoma;  
 RA, rheumatoid arthritis; SLE, systemic lupus erythematosus; UC, ulcerative colitis

# GALARISSO TYK2 '3667 Ph2 in DM

*Topline data expected 2025*

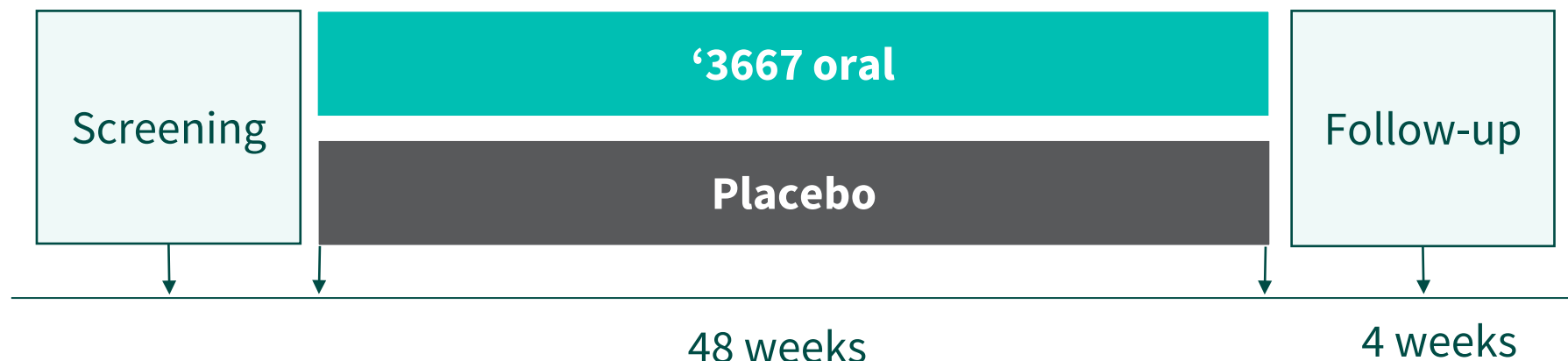


## Adults with active dermatomyositis and reduced muscle strength

- **Primary endpoint:** proportion of subjects with improvement at Week 24 according to ACR/EULAR criteria\*
- **Secondary endpoints:** change from baseline in m-CDASI-A, safety/tolerability, PK

# GALACELA TYK2 '3667 Ph2 in SLE

*Study initiated; topline data expected 2026*

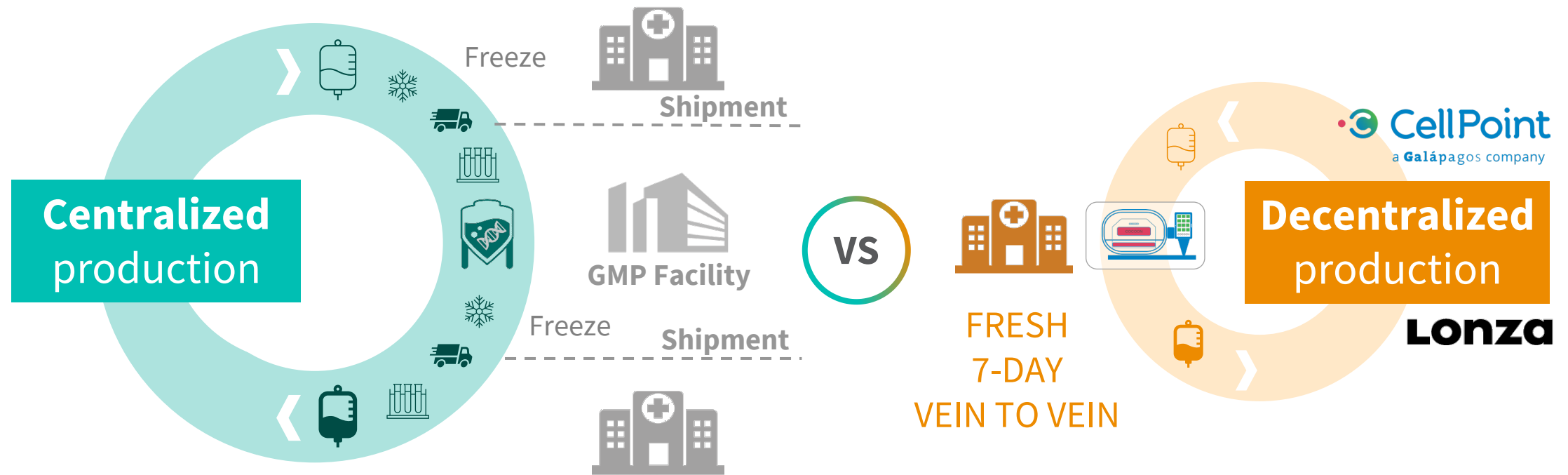


**Adults with active systemic lupus erythematosus (N≈140)**

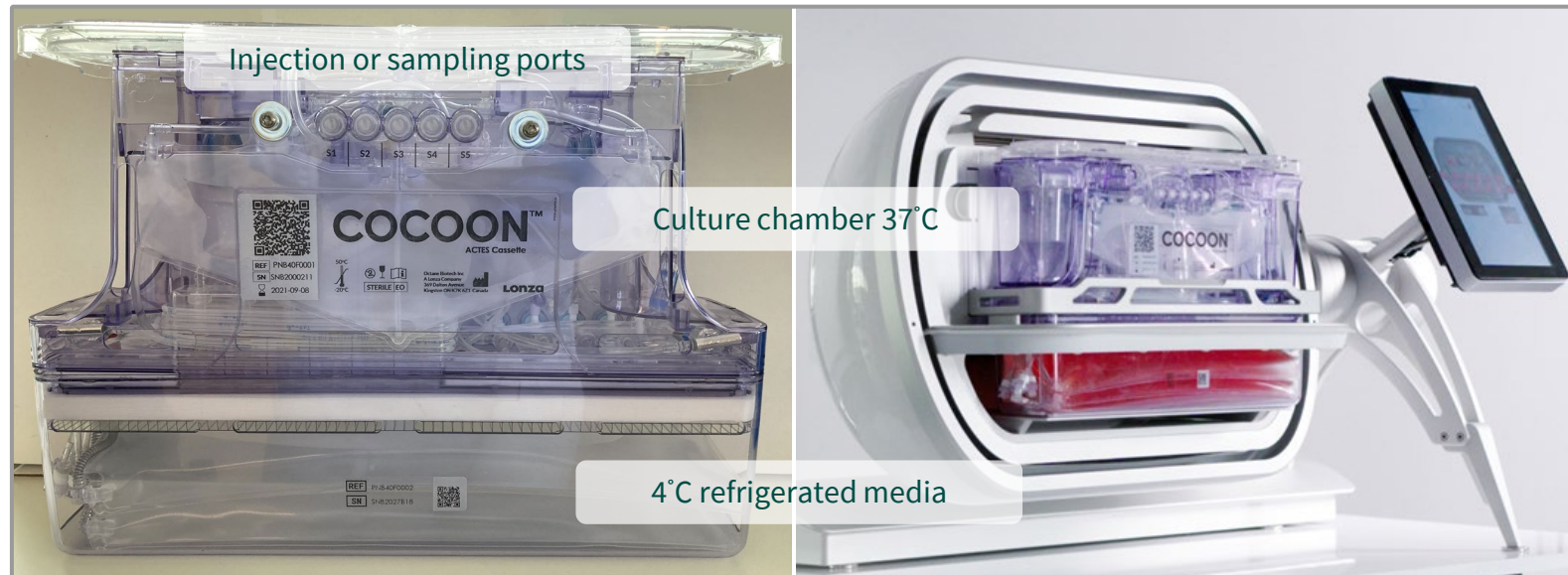
- **Primary endpoint:** proportion of subjects with improvement at Week 32 according to SLE Responder Index (SRI)-4
- **Secondary endpoints:** proportion of subjects achieving BICLA, CLASI-A, LLDAS scores, joint count readouts, safety/tolerability, PK

# Increase patient access with point-of-care delivery of CAR-T cell therapies

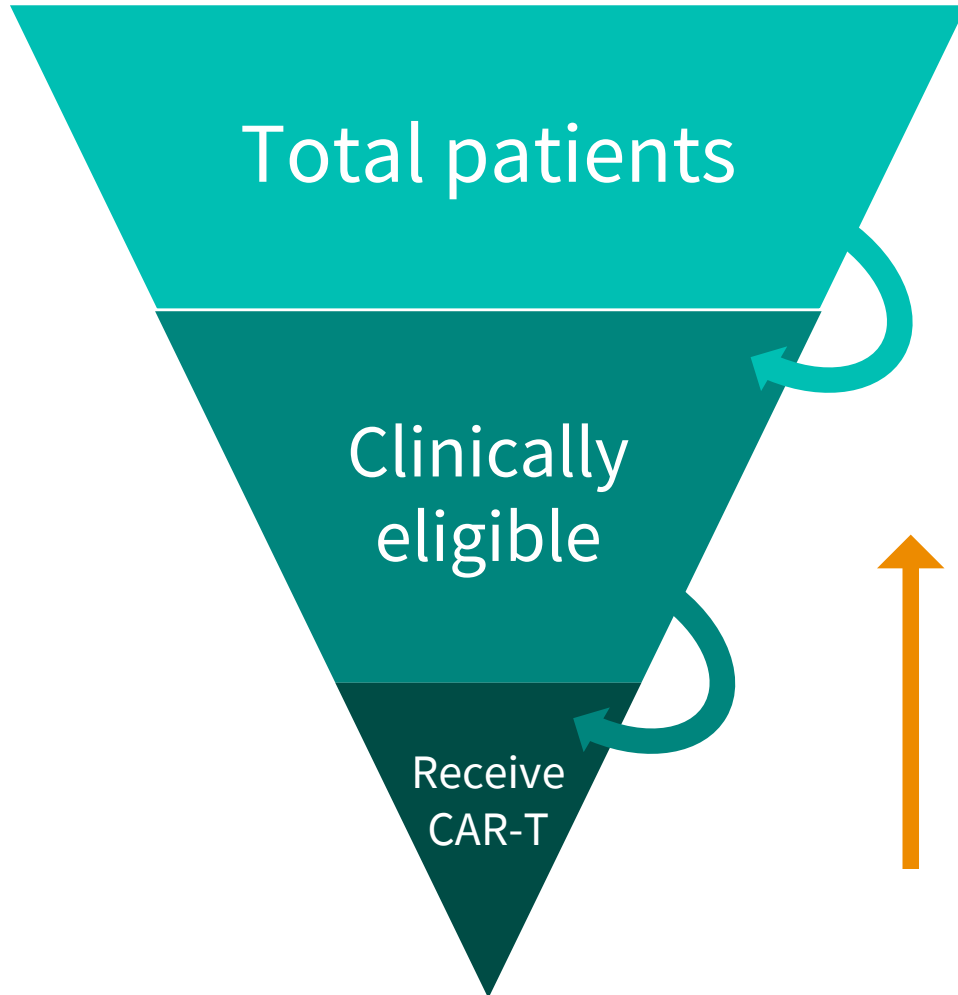
*Offer potential for rapid, automated and scalable CAR-T treatment*



# Cocoon<sup>®</sup>: fully-closed sterile system for CAR-T



# Leverage CAR-T point-of-care solution



## High unmet need cancer patient populations can benefit from CAR-T

- Fast-progressing cancers
- Poor prognosis/short life expectancy
- No standardized treatment strategy

## Significant barriers - <10-20% of eligible patients receive CAR-T

- Length of time to secure a manufacturing slot
- Logistics & access



# ATALANTA-1 CD19 CAR-T Ph1/2a in r/rNHL

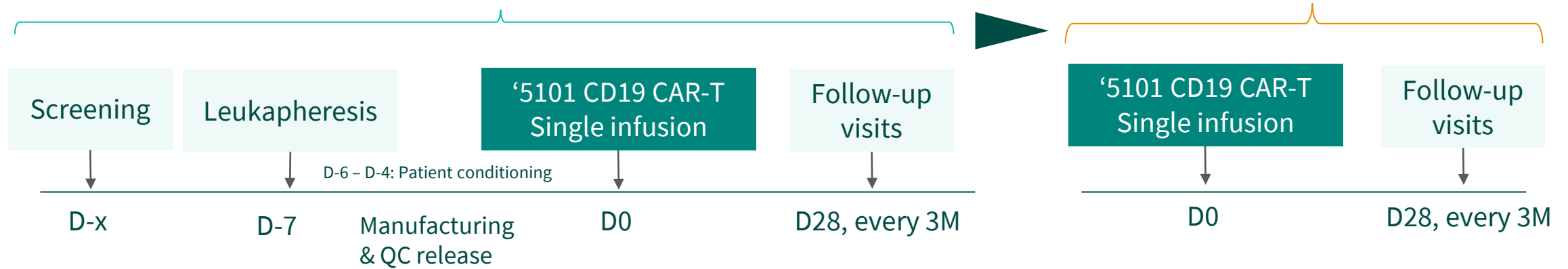
**GLPG5101 'basket trial' in DLBCL, MCL, FL, MZL**

## Ph1 - dose escalation (n≈15)

- DL1 '5101 (low)
- DL2 '5101 (medium)
- DL3 '5101 (high)

## Ph2 - dose expansion (n≈30)

- '5101 RP2D dose



**Reported encouraging first results (ORR 86%, CRR 86%)**  
**No Grade ≥3 CRS/ICANS; Median vein-to-vein time of 7 days**

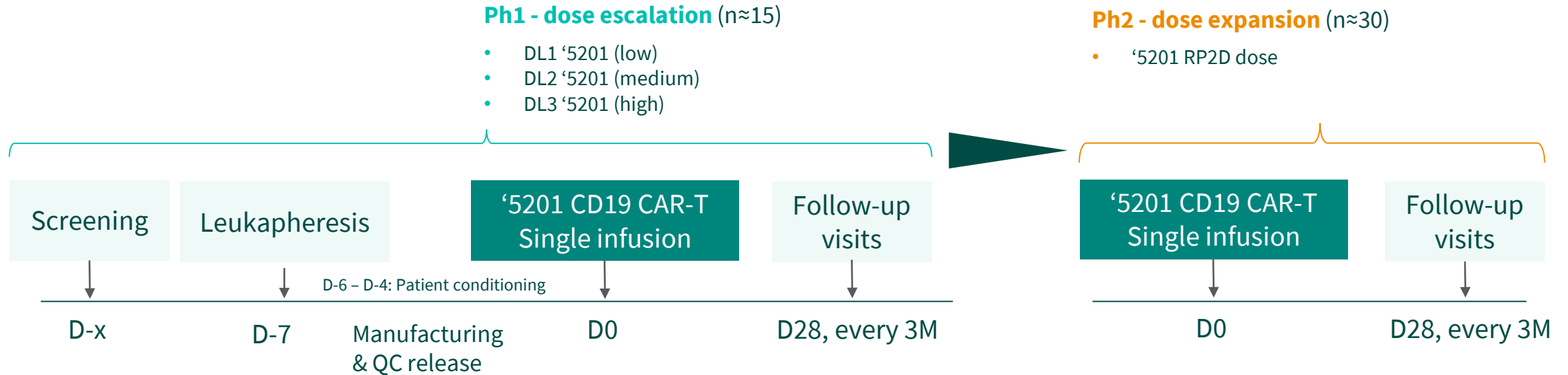
# Progress with GLPG5101 in r/rNHL

*Building robust data package & support submission for pivotal study*

- Recruiting additional patients for specific subpopulations
- Actively dosing first patients with indolent lymphoma & MCL in Ph2 dose expansion
- First US point-of-care manufacturing site selected
- Preparing US IND submission (planned for H1 2024)

**Abstract submitted to upcoming scientific conference**

# EUPLAGIA-1 CD19 CAR-T Ph1/2a in r/rCLL



**Reported encouraging first results (ORR 100%, CRR 86%)**  
**No Grade ≥3 CRS/ no ICANS; Median vein-to-vein time of 7 days**

# Progress with GLPG5201 in r/rCLL

*Incl. patients with Richter's transformation (RT)*

- Ph1 recruitment almost completed
- Plan to initiate the Ph2 dose-expansion part in H1 2024
- RP2D dose based on safety profile, efficacy & CAR-T cell expansion & persistence
- Preparing US IND submission (planned for H1 2024)

**Abstract submitted for upcoming scientific conference**



# Discovery portfolio

# Accelerating our portfolio



## Shorter time to patients

- Strong TA expertise
- Combine internal & external innovation
- From first-in-class to best-in-class targets
- Focus on transformational products in high unmet medical needs



# Rejuvenated Discovery portfolio

*Building on innovative biologics discovery and expertise in small molecules*

IMMUNOLOGY	ONCOLOGY
Cell therapy	
<ul style="list-style-type: none"><li>Fully-human CD19 CAR-T targeting unique epitope with differentiated binding kinetics (PCC nominated)</li></ul>	<ul style="list-style-type: none"><li>&gt;5 targets across heme &amp; solid cancers</li><li>Multiple differentiated armoring strategies to enhance CAR-T performance &amp; durability</li></ul>
Small molecules	
<ul style="list-style-type: none"><li>&gt;5 targets across indications identified</li><li>Different stages of preclinical development</li></ul>	<ul style="list-style-type: none"><li>&gt;5 targets across cancer types identified</li><li>Deliver precision medicines</li></ul>

**Aim to nominate several clinical candidates in 2024**

# Agenda

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# Jyseleca<sup>®</sup> EU net sales of €28M in Q2 2023

*FY23 guidance adjusted to €100-120M (previously €140-160M)*

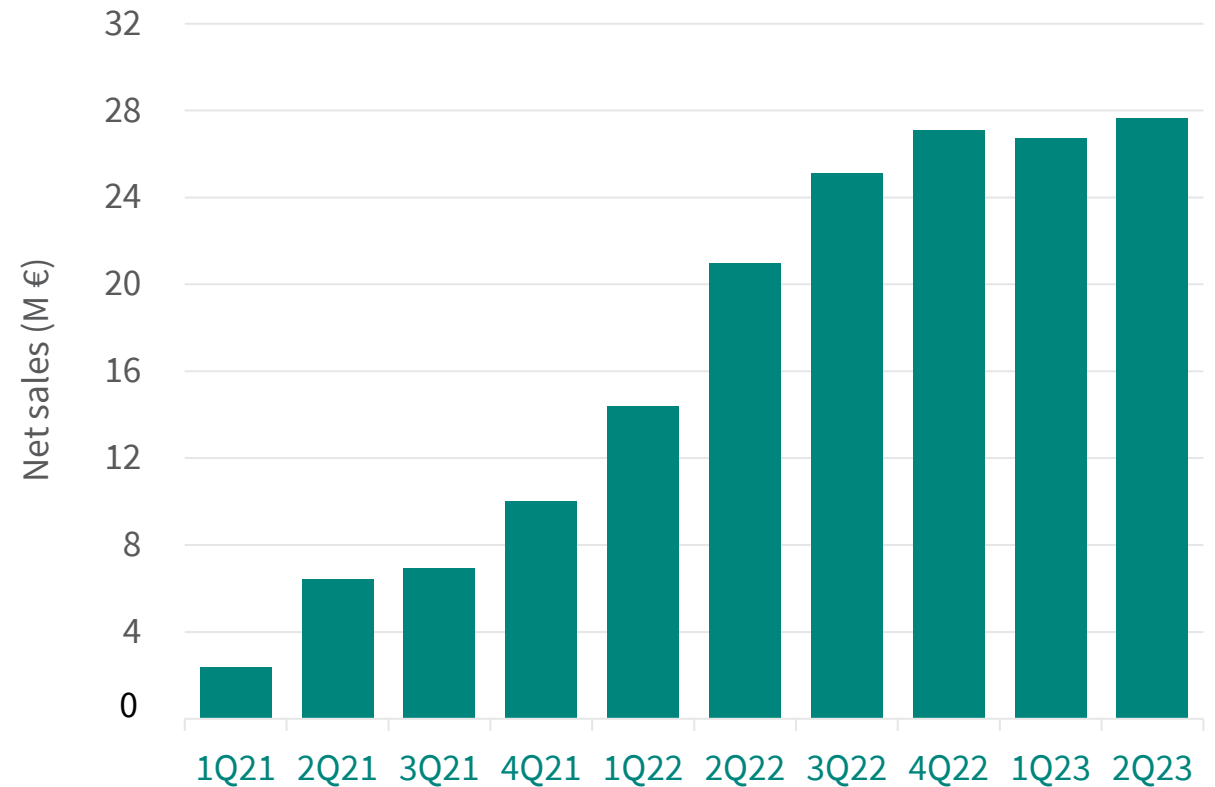
Approved for RA (~85%) & UC (~15%)

Treating >18,800 patients

Pressure on sales

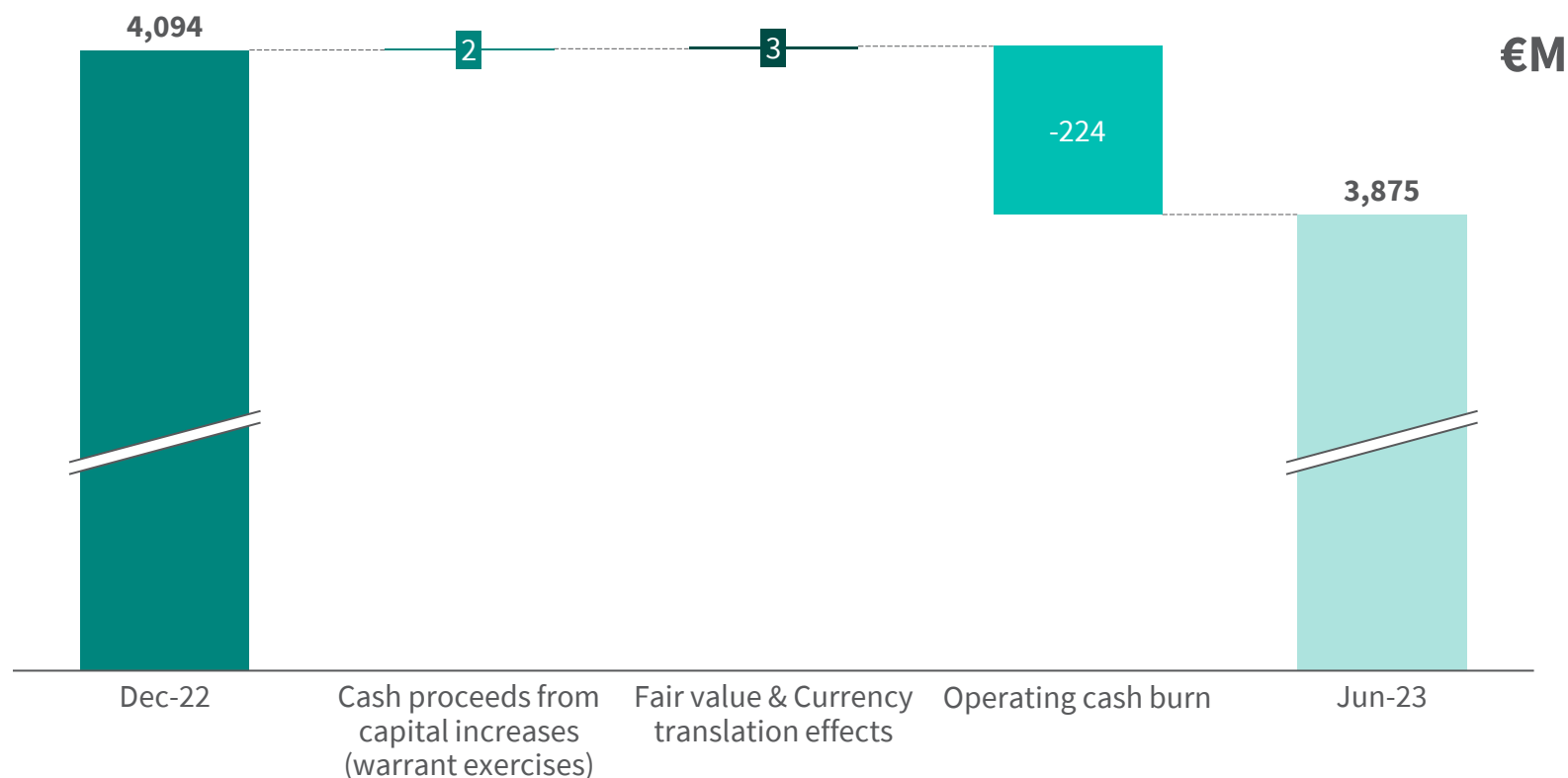
- JAKi dynamic class impacted by PRAC Art. 20 (Q4 '22)
- IBD opportunity affected by CD readout (Q1 '23)

**Evaluating strategic options**



# Cash & Current Financial Investments

**Cash burn of €224M; cash position of ~€3.9B end of June 2023**



**Reiterating FY23 cash burn guidance of €380-420M**

# Key financials H1 2023

€353M

## *Revenues & other income*

- €155M revenue recognition for filgotinib development
- €115M revenue recognition for platform
- €54M sales, €1M sales milestones & €3M royalties for Jyseleca®

-€333M

## *Operating costs*

- Decrease in R&D and SG&A costs; total opex €50M down (-13%) vs last year

€28M

## *Net profit*

- €31M net financial income

# Our approach to partnering and M&A

*BD to accelerate pipeline in immunology & oncology*

## What do we look for?

- Fast access-to-market
- Late pre-clinical/early clinical stage
- Commercial leverage in Europe
- TA focus on immunology & oncology
- Unmet medical needs
- 'String-of-pearls' approach

## What do we bring?

- End-to-end development capabilities
- Strong leadership; entrepreneurial mindset
- Commercial infrastructure in EU
- Collaboration partner Gilead
- Solid balance sheet



# Outlook 2023

## Data read-outs

- '5101 CD19 CAR-T Ph1 NHL
- '5201 CD19 CAR-T Ph1 CLL



## Regulatory progress

- BCMA CTA in MM approval ✓
- CD19 IND preparation in oncology
- '5101 CD19 CTA in rSLE submitted ✓



## Trial initiations

- Filgotinib Ph3 AxSpa ✓
- '3667 (TYK2i) Ph2 DM ✓
- '3667 (TYK2i) Ph2 SLE
- '5101 CD19 CAR-T NHL expansion cohorts ✓
- '5201 CD19 CAR-T CLL expansion cohorts
- '5301 BCMA CAR-T Ph1/2 MM
- '5101 CD19 CAR-T Ph1b rSLE



**Focused on business development opportunities**

# Continue to execute on transformation



## Accelerate early-stage pipeline

build renewed discovery portfolio



## Broaden solid late-stage pipeline

combine internal & external innovation



## Execute on oncology strategy

progress trials & expand point-of-care network



## Evaluate strategic options for Jyseleca®



## Disciplined cash use

prioritize to maximize value creation

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All

# #PioneeringForPatients

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