# 2023 Year in Review

*23 Feb 2024*

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,” “believe,” “anticipate,” “plan,” “continue,” “forward,” “goal,” “should,” “expect,” “outlook,” “estimate,” “next,” “encouraging,” “ aim,” and “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 2024, statements related to the transfer of Jyseleca® to Alfasigma, including potential cost savings, and milestone payments, 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 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 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, and statements and expectations regarding the rollout of our products or product candidates (if approved). 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 2024 cash burn may be incorrect (including because one or more of the assumptions underlying our cash burn 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 (and employees exclusively dedicated to these activities) to NovAliX, the risk that we may not realize the anticipated benefits of the transaction with Alfasigma, 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 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 and EUPLAGIA-1 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 estimates regarding the commercial potential of our product candidates will be incorrect, and 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. 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 results 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 | Driving value creation | Dr. Paul Stoffels*, CEO |
| 2 | Operational & financial update | Thad Huston, CFO & COO |
| 3 | Outlook | Dr. Paul Stoffels*, CEO |
| 4 | Q&A | All |

*Throughout this presentation, 'Dr. Paul Stoffels' should be read as 'Dr. Paul Stoffels, acting via Stoffels IMC BV'

# Realizing company turnaround to drive value

**Patient-centric, therapeutic area focus**
Best-in-class immunology, oncology drugs

**Pure play biotech**
End-to-end R&D capabilities with a focus on breakthrough medicines and high-unmet needs

**Internal and external innovation**
Redesigned early discovery – different modalities

**Streamlined, lean organization**
~700 employees* in BE, NL, CH, FR and the US

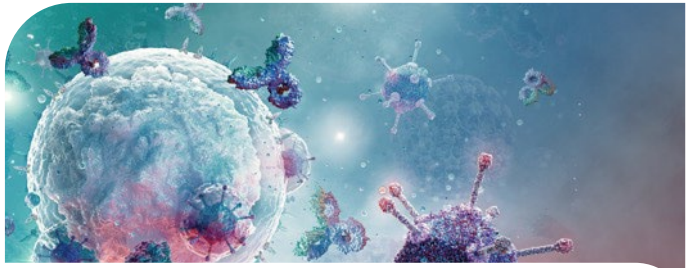
**Significant cash burn reduction**
2024 guidance of €280M-320M

Galápagos

*As per February 6, 2024
BE, Belgium; CH, Switzerland; FR, France; NL, the Netherlands

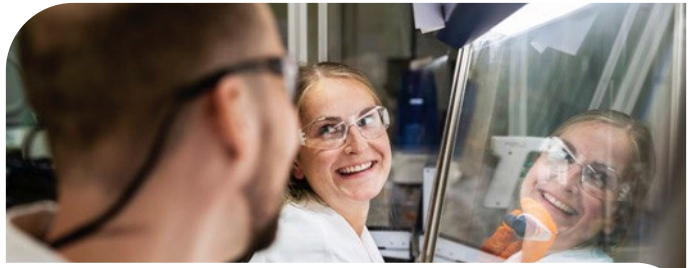
# Unlocking value with groundbreaking solutions

***We combine deep disease expertise and multiple drug modalities to focus on high unmet medical needs and accelerating time-to-patients***



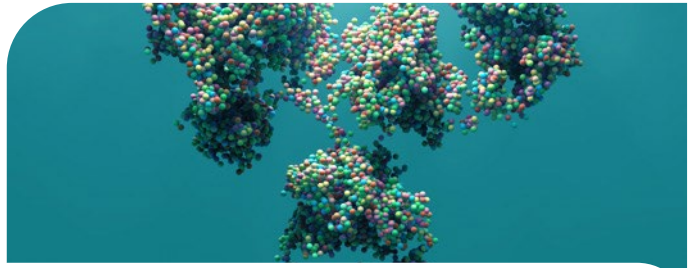
### Cell Therapy

We have groundbreaking research capabilities and a decentralized manufacturing platform for CAR-T



### Small Molecules

We have a long history and deep R&D expertise in small molecules



### Biologics

We are building research capabilities to discover novel biological medicines

# Focusing on accelerating our pipeline

## IMMUNOLOGY

| PROGRAM | CLASS | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | APPROVED |
|---|---|---|---|---|---|---|
| 3667 | TYK2 | | | SLE & DM | | |
| | Multiple targets | | | | | |

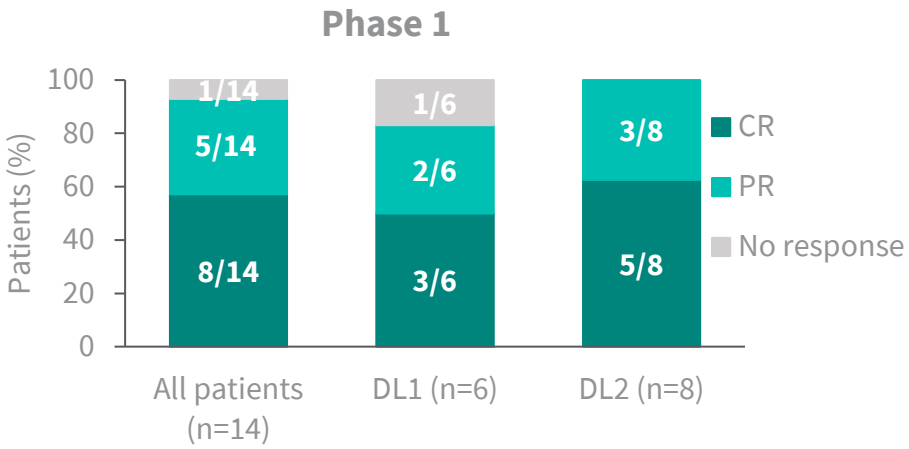
## ONCOLOGY

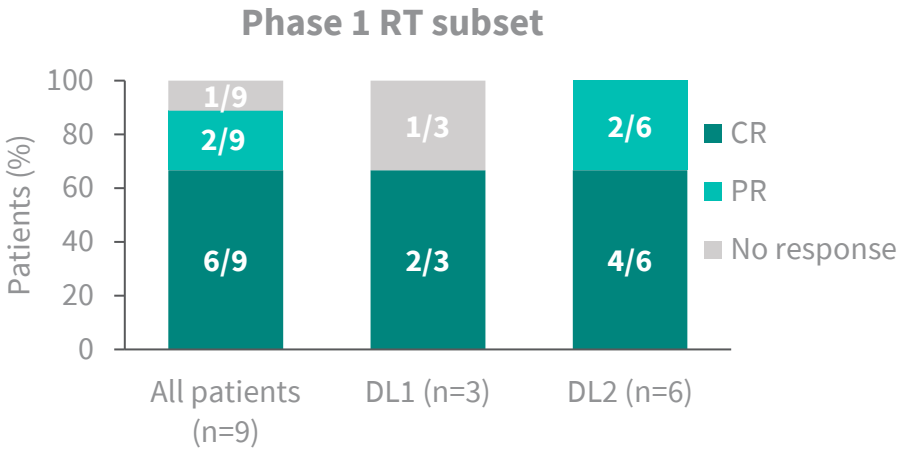
| PROGRAM | CLASS | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | APPROVED |
|---|---|---|---|---|---|---|
| 5101 | CD19 CAR-T | | | NHL | | |
| 5201 | CD19 CAR-T | | CLL & RT | | | |
| 5301 | BCMA CAR-T | MM | | | | |
| | Multiple targets | | | | | |

CLL, chronic lymphocytic leukemia; DM, dermatomyositis; MM, multiple myeloma; NHL, non-Hodgkin lymphoma; SLE, systemic lupus erythematosus

# Encouraging results with 5201 in ongoing EUPLAGIA-1 Ph1/2 study in rrCLL and RT

## *Preliminary Ph1 results in heavily pretreated patient population*




- 13/14 patients responded (**ORR 93%**)
- 8/8 patients on **DL2** responded (**ORR 100%)**
- 8/14 patients reached a complete response (**CRR 57%)**
- 5/8 on **DL2** reached a complete response (**CRR 63%)**
- Median follow-up of 6 months (follow-up up to 15 months)

- 8 of 9 patients with RT responded (**ORR 89%**)
- All 6 RT patients on **DL2** responded (**ORR 100%**)
- 6 of 9 RT patients reached a complete response (**CRR 67%**)

## *Encouraging safety profile*

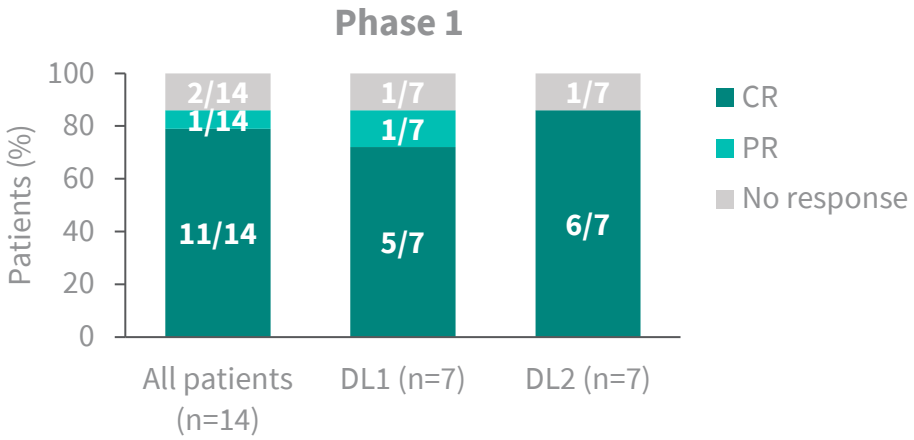
- ‘5201 is well-tolerated
- No CRS ≥ Grade 3
- No ICANS reported

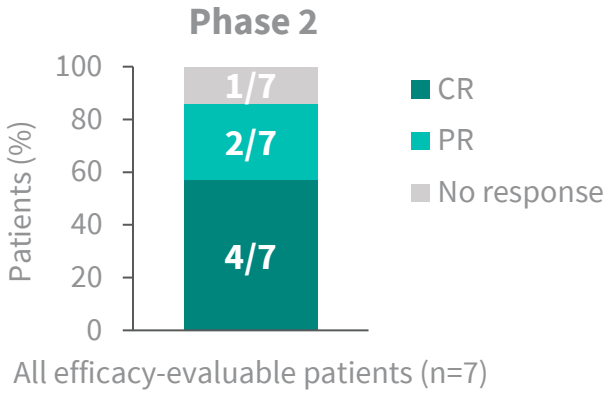
Data presented at ASH 2023 (Tovar N, et al.) ASH poster #2112, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 6 September 2023.
Combined response, iwCLL for CLL patients without RT and Lugano classification for patients with RT. DL1: 35E6 CAR-positive viable T cells, DL2: 100E6 CAR-positive viable T cells. CR, complete remission; CRR, CR rate; CRS, cytokine release syndrome; DL, dose level; ORR, objective response rate; ICANS, Immune effector cell-associated neurotoxicity syndrome ; RT, Richter Transformation; PR, partial response; rrCLL, relapsed refractory chronic lymphocytic leukemia

Galápagos

# Encouraging results with 5101 in ongoing ATALANTA-1 Ph1/2 study in rrNHL

## *Preliminary results in heavily pretreated patient population*




- 12/14 patients responded (**ORR 86%**)
- 11/14 reached a complete response (**CRR 79%**)
- **CRR** of **86%** in **DL2** (6/7 patients)
- Median follow-up of 8.6 months (follow-up up to 15 months)

- 7/9 patients were efficacy-evaluable (D28 reached)
- 6/7 patients responded (**ORR 86%**)
- 4/7 reached a complete response (**CRR 57%**)
- Median follow-up of 3.2 months

## *Encouraging safety profile*

**1 case of Grade 3 CRS**

- All other Grade 1-2

**1 case of Grade 3 ICANS**

- All other Grade 1

**2 deaths**

- 1 intra-abdominal hemorrhage* in patient previously diagnosed with prior thromboembolic disease on LMWH
- 1 urosepsis >6 months post-infusion**

Galápagos

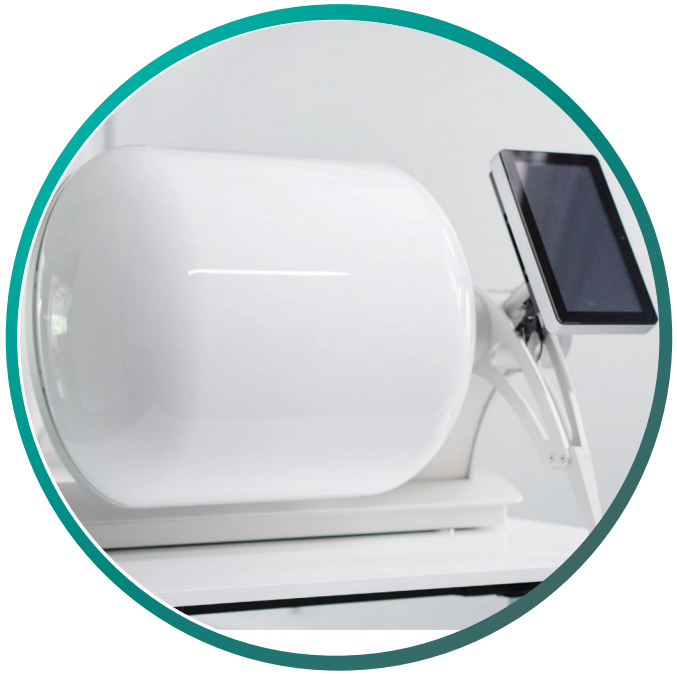
Data presented at ASH 2023 (Kersten MJ, et al. ). ASH poster #2113, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 1 September 2023
DL1: 50E6 CAR-positive viable T cells, DL2: 110E6 CAR-positive viable T cells. CR, complete remission; CRR, complete response rate; CRS, cytokine release syndrome; DL, dose level; ICANS, Immune effector cell-associated neurotoxicity syndrome; LMWH, low-molecular-weight heparin; ORR, objective response rate; PR, partial response; rrNHL, relapsed refractory non-Hodgkin lymphoma
* 12 days post infusion; ** > 6 months after infusion while patient was in ongoing CR

# Building out global point-of-care network

*With the Lonza Cocoon®*

## Finalizing tech transfer to 1st US site

Boston-based Landmark Bio



## 3rd clinical CAR-T study on point-of care

PAPILIO-1 Ph1/2 study in rrMM launched

## Signing additional sites

SF-based Thermo Fisher

## Strengthening capabilities

Including quality, regulatory

## Adding clinical sites globally

5 clinical trial sites in EU

Galápagos

The Cocoon® Platform is a registered trademark of Lonza Group AG
rrMM, refractory relapsed multiple myeloma

# Strengthening the organization to drive value

***Focusing our research and development efforts***

- **NovAliX & Jyseleca® transactions completed**
  - Significant cost savings
  - Redeployment of resources
- **Disciplined cash use** for **internal** and **external** pipeline expansion
- Increase **capabilities** & **expertise** to support growth in key TAs, including U.S. footprint



TA, therapeutic area

# Transferred Jyseleca® to Alfasigma

## *Strategically and financially compelling transaction*

**€50M Upfront Payment**

Potential milestone payments totaling €120M*

**Royalties**

Mid-single to mid-double digit royalties on European sales

**Streamlining Organization**

~400 positions transferring & optimizing ~100

**Considerable Savings**

Estimated annualized savings between €150M-200M**

**Investing in Future Growth**

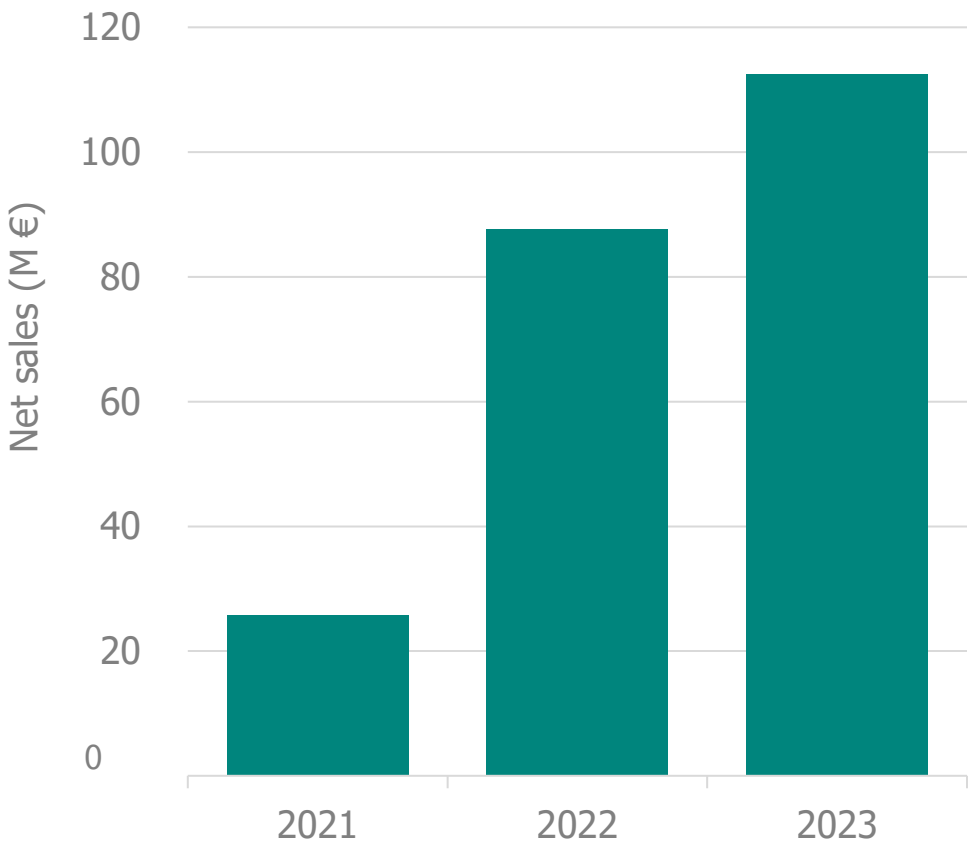
Frees up significant resources, enabling more R&D investment

## Delivered on commitment to take action for Jyseleca®

Potential milestone payments, employee transfers and cost savings are based on current Galapagos estimates
*Galapagos will contribute up to €40M to Alfasigma by June 2025 for Jyseleca® related development activities
** starting in 2025

# Jyseleca® performance in Europe

- €112M in net sales full year 2023 (€30M 4Q23)
- Within restated guidance of €100M-120M
- Approved for RA & UC across Europe
- Treating >21,000 patients
- Transaction with Alfasigma closed on 31 January ‘24




Galápagos

RA, rheumatoid arthritis; UC, ulcerative colitis

# Key financials 2023

| Millions of € | 2023 | 2022 | % change |
|---|---|---|---|
| Collaboration revenues | 240 | 241 | -1% |
| **Total revenues** | **240** | **241** | **-1%** |
| R&D | (241) | (270) | -11% |
| G&A, S&M | (134) | (139) | -3% |
| Other operating income | 47 | 36 | +31% |
| **Operating loss** | **(88)** | **(131)** | **-33%** |
| Net financial result | 94 | 60 | |
| Income taxes | (10) | (1) | |
| **Net loss continuing operations** | **(4)** | **(71)** | |
| Net profit/loss discontinued operations | 216 | (147) | |
| **Net profit/loss** | **212** | **(218)** | |

## FY23 revenues flat YoY

- €230M revenue recognition for platform
- €9.5M royalties for Jyseleca®

## Disciplined expense management

- Decrease in R&D (-11%) and SG&A (-3%) YoY
- Total opex €33M down (-8%) YoY

## Net profit gain driven by

- €431M **collaboration revenues** for filgotinib
- €94M net financial income

# 2023 continued and discontinued operations

| 2023 - Millions of € | Continuing operations | Discontinued operations | Total group |
|---|---|---|---|
| Product net sales | | 112 | 112 |
| Collaboration revenues | 240 | 431 | 671 |
| **Total revenues** | **240** | **544** | **784** |
| Cost of sales | | (18) | (18) |
| R&D | (241) | (190) | (431) |
| S, G&A | (134) | (131) | (265) |
| **Total operating expenses** | **(375)** | **(322)** | **(697)** |
| Grant & Other income | 47 | 13 | 60 |
| **Operating profit/(loss)** | **(88)** | **217** | **129** |
| Financial result | 94 | 0 | 94 |
| Income taxes | (10) | (2) | (12) |
| **Net profit/loss** | **(4)** | **216** | **212** |

## Positive catch-up released to revenues

- €112M Jyseleca® sales, within guidance
- €431M collaboration revenues for filgotinib due to positive catch-up effect (closing Alfasigma transaction)

## Decreased filgotinib development costs

- Discontinuation of Ph3 trial in CD
- Reduced personnel expenses, subcontracting and outsourcing costs

Galápagos

CD, Crohn's disease

# 2024 guidance

***Cash burn reduced due to Jyseleca transfer***

***Redeploy resources to invest in our business and pipeline for value creation***

## 2023

**€415M**

Cash burn (€380-420M)

**~€3.7B**

Cash position*

## 2024

**€280-320M**

Guidance

Excludes potential BD

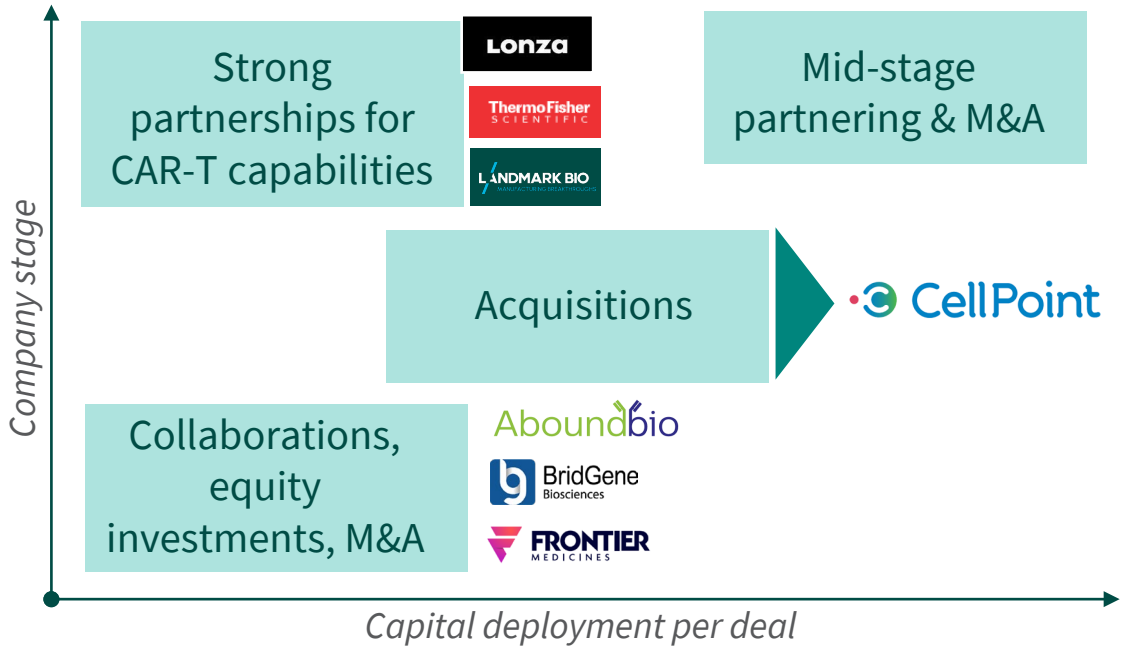
Galápagos

*as of end of December 2023
Guidance based on current Galapagos estimates

# Disciplined business development to accelerate portfolio

*Executing on multiple deals across oncology & immunology*

**Strategic highly selective partnering**



# Outlook 2024

## *Regulatory progress*

- IND submission ‘5101 CD19 CAR-T in rrNHL
- IND submission ‘5201 CD19 CAR-T in rrCLL and RT

## *Trial progress*

- Start Ph2 expansion cohort in U.S. ‘5101 CD19 CAR-T rrNHL (ATALANTA)
- Ph2 expansion in EU ‘5201 CD19 CAR-T rrCLL & RT (EUPLAGIA)
- Ph1/2 expansion in EU ‘5301 BCMA CAR-T in rrMM (PAPILIO)

## *Data readouts*

- Update Ph1/2 ‘5101 CD19 CAR-T in rrNHL (ATALANTA)
- Update Ph1/2 ‘5201 CD19 CAR-T in rrCLL & RT (EUPLAGIA)
- Update Ph1/2 ‘5301 BCMA CAR-T in rrMM (PAPILIO)

## *Business development activity*

- Additional partnerships for CAR-T PoC network
- License agreements and/or acquisitions
- Research collaborations & equity investments

FPI, first patient in; IND, investigational new drug; rrCLL, refractory relapsed chronic lymphocytic leukemia; rrMM, refractory relapsed multiple myeloma; rrNHL, refractory relapsed non-Hodgkin lymphoma
Based on Galapagos management expectations and estimates

# We have a clear path outlined for value creation

***Strong fundamentals to build a global innovative biotech***

**Progress early-stage pipeline**

Build on renewed discovery portfolio

**Broaden product portfolio**

Execute on BD opportunities

**Deliver on scientific progress**

Advance trials in immunology & oncology

**Strengthen capabilities**

Build world-class R&D team

**Strong cash balance**

Disciplined spending to maximize value creation

**Delivering on *Faster, Forward* strategy to unlock value**

# #PioneeringForPatients

*Follow us @GalapagosNV | GLPG.com*