# Autolus

# Third Quarter Financial Results and Operational Progress



November 2, 2023

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## Agenda

- Welcome and Introduction: Julia Wilson Communications Consultant
- Operational Highlights: Dr. Christian Itin, CEO
- Financial Results: Rob Dolski, CFO
- Upcoming Milestones and Conclusion: Dr. Christian Itin, CEO
- Q&A: Dr. Christian Itin and Rob Dolski

## **Obe-cel highlights**

Continued progress against strategic and operational goals

	Clinical	•	obe-cel in relapsed / refractory (r/r) adult ALL
			<ul> <li>Oral presentation on longer follow up of FELIX study at ASH conference on Dec 9, 2023</li> </ul>
			<ul> <li>Initiation of pediatric Phase 1 study in Q4 2023</li> </ul>
	Manufacturing	•	Robust manufacturing process and state of the art commercial manufacturing
			<ul> <li>Process performance qualification at the Nucleus facility completed and on track to support BLA filing</li> </ul>
			<ul> <li>Poster presentation at ASH on obe-cel manufacturing performance</li> </ul>
	Regulatory	•	Filing of Biologics License Application (BLA) to the US Food and Drug Administration (FDA) on track for end of 2023
		•	Marketing Authorization Application (MAA) to EMA H1 2024
			Autolus' commercial capability and infrastructure preparation on track
	Commercial Readiness		<ul> <li>Commercial systems setup on track</li> </ul>
			<ul> <li>Focus on clinical center onboarding and medical affairs</li> </ul>

#### Other pipeline highlights during the period

# Obe-cel and AUTO1/22

#### Expanding the obe-cel opportunity

- Phase 1 dose confirmation study in refractory systemic lupus erythematosus (SLE) to start in early 2024
- ALLCAR19 extension study of obe-cel in r/r B-NHL and CLL will complete enrollment in 2023
- CD19 and CD22 dual targeting in pediatric ALL
  - CARPALL Phase 1 trial of AUTO1/22 in pediatric ALL data published in Blood and Nature Medicine
- MCARTY Phase 1 trial of AUTO8 in Multiple Myeloma continues to enroll patients with first data at ASH in Dec 2023
  - Oral presentation at ASH conference on Dec 9, 2023
- Phase 1 trial of AUTO6NG in Neuroblastoma, first patient expected to be dosed in Q4 2023



### LEAD CLINICAL PROGRAM Obe-cel

A standalone, potentially best-in-class CD19 CAR T cell therapy candidate

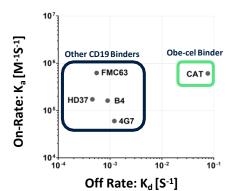
## Obe-cel has a unique mechanism of action

Designed for increased activity and reduced toxicity

#### **Differentiated CD19 binder**



#### Fast off-rate



Shorter half-life of interaction compared to binders used in approved products

#### • obe-cel = 9.8 seconds

• Kymriah<sup>®</sup> = 21 minutes

#### Potential for improved potency, reduced toxicity

- Avoids over-activation of CAR T cells
- Increases CAR T peak expansion
- Avoids exhaustion of CAR T-cells

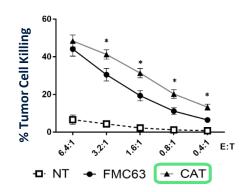


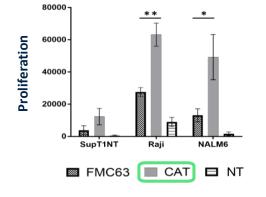
**Reduced toxicities** 

Improved persistence

Improved engraftment Improved persistence

#### Enhanced cytotoxicity and proliferation





Ghorashian et al. Nature Medicine 2019

#### Summary of FELIX data at ASCO and EHA 2023

- CR/CRi rate of 76%, with 97% of responders becoming MRD negative
  - With a median of 9.5 months' follow-up, 61% of responders remain in remission
- Very low rates of Grade ≥3 CRS (3.2%) and low rates of Grade ≥3 ICANS (7.4%)
  - In total, obe-cel was evaluated in 94 patients with r/r B-ALL
  - 31% of patients had received ≥3 prior lines of therapy and 33% had >75% marrow burden at infusion
- Robust manufacturing process, with product released for 94% of leukapheresed patients
  - 84% of enrolled patients received obe-cel
  - Median vein to release of 21 days
- Excellent CAR T-cell engraftment
  - C<sub>max</sub> of 114,982 copies/ug DNA and Tmax at 14 days

#### Data updates planned for ASH, December 9 – 12, 2023

Abstracts published online today



Obe-cel: Oral presentation of FELIX study - pooled analysis of Phase Ib and Phase II cohorts Saturday, December 9, 2023, 3.15 pm PT

- Focus on longer follow up and subgroup analysis
- Data continued to demonstrate high rates of CR/CRi and a favorable safety profile
- In a subgroup of patients data suggest better outcomes in patients with low leukemia burden

#### Obe-cel: Pooled analysis from ALLCAR19 and FELIX, and ALLCAR19 extension

- Focus on pooled analysis of long-term follow up of ALL patients treated in ALLCAR19 and FELIX Phase Ib studies
- Additional f/u of patients with CLL and B-NHL treated with obe-cel indicate very high sustained response rates achieved with well tolerated safety profile



Obe-cel: CMC demonstrating the robustness of obe-cel manufacturing

- Review of product delivery performance during FELIX study:
  - Process design to cope with high leukemic blast counts containing leukapheresates
  - Improved analytics to minimize turnaround time



- AUTO8: Initial results from Phase I MCARTY study in multiple myeloma
- Clinical responses seen in 6/6 evaluable patients
- Doses well tolerated, no ≥ Grade 3 ICANS or CRS

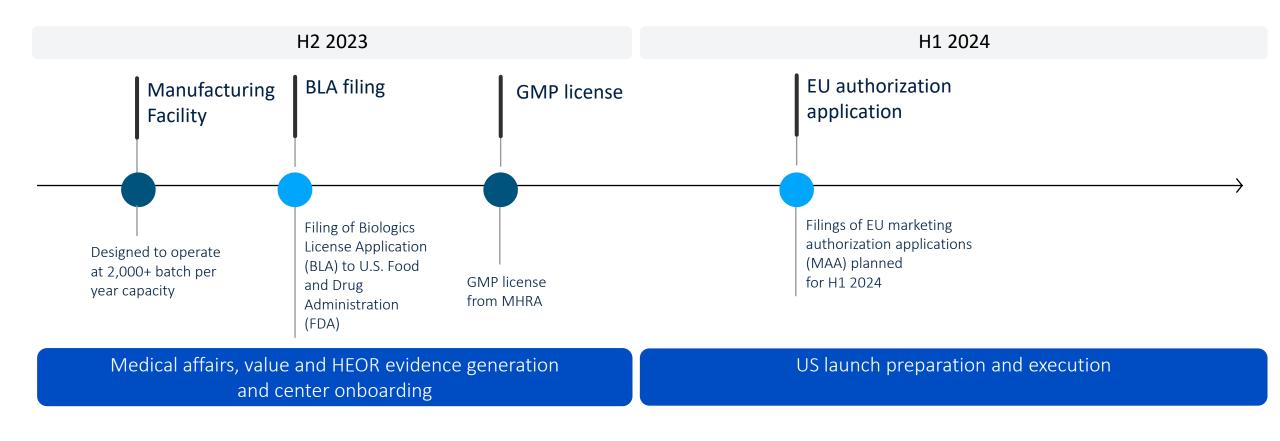
Abstracts can be viewed via the ASH abstract portal, Roddie C et al, # 222, Roddie C et al, #2114, Merges M et al., #4892; Lee L et al., #350



## **Commercial Launch Readiness**

#### Obe-cel steps to commercialization

Roadmap to a 2024 commercial launch



Regulatory

Manufacturing

Commercialization

## **The Nucleus**

State of the art design and operations established – validation completed

#### Design



- ~70,000 sq ft facility
- Modular build using PAMs
- 70% built off-site
- 60% reduced build time
- BREEAM Excellent rating for sustainability

- - Nov 8, 2021 ground breaking
  - Nov 25, 2022 first clean room in operation

**Build** 

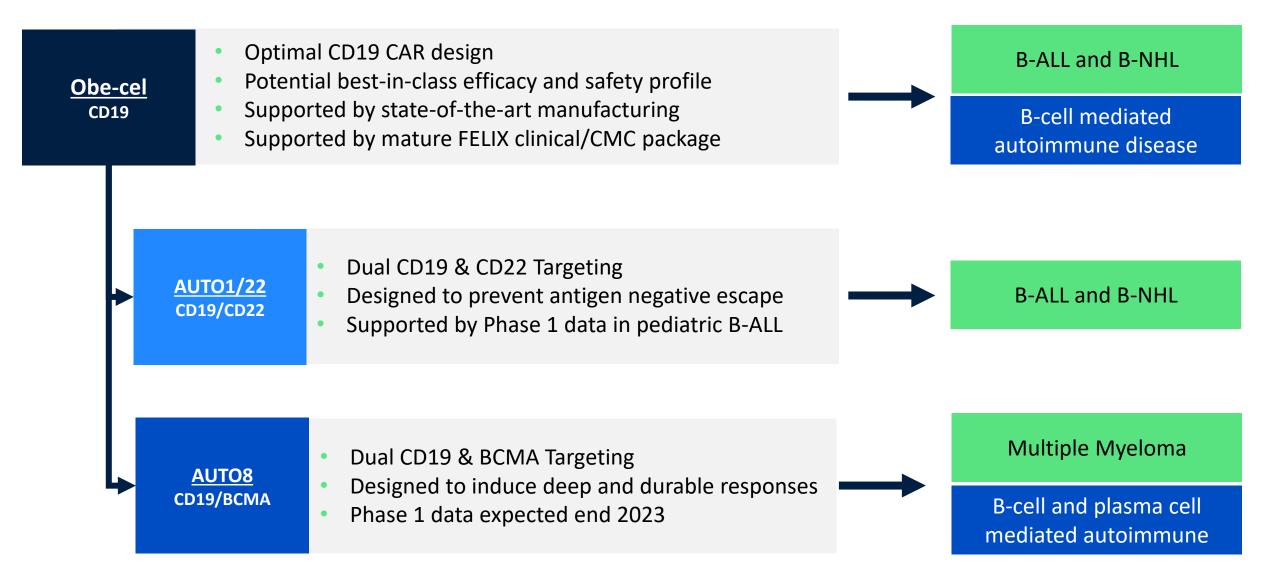
 Facility validation completed in 2H 2023 Dec 14, 2022 first Prodigy operational

**Operations** 

- May 2023 capacity challenge
- Designed for 2,000+ batches per year
- Target vein to delivery time 16 days at launch

Building the obe-cel opportunity and pipeline

#### The obe-cel product family and franchise opportunity



#### Uniquely positioned to deliver CAR T therapy in autoimmune disease

#### **Obe-cel's potential advantages**

Outstanding tolerability to drive physician and patient acceptability in rheumatology settings

Deep cut into the CD19+ B and plasma cell compartment to remove all autoreactive clones

Development of robust, economical and scalable manufacturing and commercial infrastructure

High treatment effect enables smaller clinical program and accelerated regulatory path to launch

#### Supporting evidence

- Potential best-in-class risk/benefit profile in pivotal FELIX trial in adult ALL
- Low rates of high-grade CRS and ICANS across all patients

- Demonstrated in B-ALL with very high rate of MRD negative complete remissions (97% of responders)
- Potential approved, commercial manufacturing facility in adult ALL with attractive cost of goods at launch for SLE
- Commercial systems and CAR T center services established with potential adult ALL launch
- ✓ Treatment effect demonstrated in Erlangen proof-of concept
- Clinical safety data from ALLCAR19 and FELIX as well as potential commercial patient data to supplement SLE pivotal study

## Obe-cel ideally positioned as potential best in class and fastest to market

Could offer fastest and lowest risk cell therapy approach for B-cell mediated autoimmune diseases

	Established Tolerability Profile	Established Clinical Profile	Manufacturing Infrastructure	Commercial Infrastructure	Comment
AUTOLUS (obe-cel)					Potential best-in-class risk/benefit ratio. Established manufacturing and product delivery. ALL commercial infrastructure in place for SLE
<b>BIOTECH</b> : (new CAR T entrants)					Clinical profile not yet established. Likely use CDMO or local site for manufacturing with unfavorable cost implications
<b>PHARMA</b> : (new CAR T products)					New products under development. Will need to re-establish efficacy & safety profile and commercial manufacturing for autoimmune
ALLOGENEIC					Clinical profile not yet established

## Autolus pipeline

PRODUCT	INDICATION	TARGET	STUDY NAME	COLLABORATION	PHASE	UPCOMING CATALYST
Obe-cel	Adult B-ALL	CD19	FELIX		Pivotal	Q4 2023: FELIX data updates Q4 2023: BLA filing with FDA
Obe-cel	Systemic Lupus Erythematosus	CD19	TBD		Preclinical	Q1 2024: Phase I initiation
Obe-cel	B-NHL and CLL	CD19	ALLCAR19	<sup>4</sup> UCL	Phase I	Data in peer reviewed journal
Obe-cel	PCNSL	CD19	CAROUSEL	<sup>≜</sup> UCL	Phase I	Data in peer reviewed journal
Allogeneic obe-cel	B-Cell malignancies	CD19	KCAT19	<sup>≜</sup> UCL	Phase I	-
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	≜UCL	Phase I	Data in peer reviewed journal
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1		Phase I	Data in peer reviewed journal
AUTO5	TRBC2+ Peripheral TCL	TRBC2	-		Preclinical	-
AUTO6NG	Neuroblastoma	GD2	MAGNETO	<sup>±</sup> UCL	CTA submitted	Q4 2023: Phase I initiation
AUTO8	Multiple Myeloma	BCMA & CD19	MCARTY	<b>≜UCL</b>	Phase I	Q4 2023: First clinical data
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD	<sup>≜</sup> UCL	Preclinical	-

## **Financial Results**

## **Financial summary**

#### Cash runway into 2025

USD	Q3 2023 (\$ '000)	Q3 2022 (\$ '000)	Variance (\$ '000)
Grant Income	-	-	-
License Income	406	2,369	(1,963)
R&D	(37,237)	(37,632)	395
G&A	(10,611)	(8,231)	(2,380)
Impairment of operating lease right-of-use assets and related property and equipment	(382)	-	(382)
Total operating expense, net	(47,824)	(43,494)	(4,330)
Other expense, net	(1,597)	(3,740)	2,143
Interest Income	3,646	165	3,481
Interest expense	(5,014)	(1,850)	(3,164)
Income tax benefit	4,940	6,152	(1,212)
Net Loss after tax	(45,849)	(42,767)	(3,082)
USD	Q3 2023 (\$ '000)	Q4 2022 (\$ '000)	Variance (\$ '000)
Cash and cash equivalents	256,415	382,436	(126,021)

• Foreign currency: 53% of cash at September 30, 2023 held in GBP

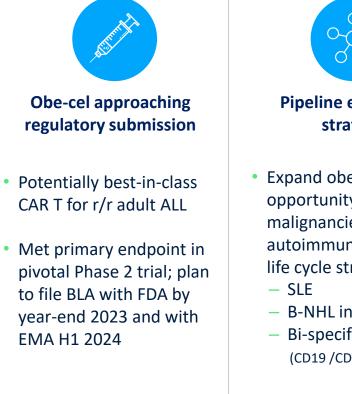
## Summary

## Autolus planned news flow

Milestone or Data Catalysts	Timing
Obe-cel Biologics License Application (BLA) to FDA	By end 2023
Obe-cel FELIX data update at ASH	Dec 2023
AUTO8 update (MCARTY) at ASH	Dec 2023
AUTO6NG Phase 1 study start (MAGNETO)	By end 2023
Obe-cel in autoimmune disease – refractory SLE Phase 1 study start	Early 2024
Obe-cel Marketing Authorization Application (MAA) to EMA	First half 2024

## Building a leading CAR T company developing transformational therapies for cancer and autoimmune diseases

Established excellence in R&D and Manufacturing; scaling company toward commercialization





**Pipeline expansion** strategy

- Expand obe-cel opportunity in B cell malignancies, autoimmune diseases & life cycle strategy
  - B-NHL indications
  - Bi-specific therapies (CD19 /CD22; CD19/BCMA)
- Expand to additional indications with novel CAR T therapies, alone or with partners



Scalable manufacturing and in-house facility

- Demonstrated reliable clinical trial supply (96% target dose reached in FELIX pivotal study)
- New commercial cell manufacturing facility in qualification stage; planned annual capacity 2,000+ batches
- Vein-to-delivery time at launch of ~16 days



**Strategic** collaborations

- Established technology collaborations with Moderna, BMS and Cabaletta
- Longstanding academic collaboration with **University College** London
- Partnering opportunities on pipeline programs and platform technology



- Runway into 2025
- Enables execution on current strategy through approval of obe-cel

# Autolus

# Thank you



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