



**OTCQB: CYTR** 

CREATING TOMORROW, TODAY.

## Corporate Overview 2<sup>nd</sup> Quarter 2020

**Non-Confidential** 

# **CytRx Safe Harbor Statement**

THIS PRESENTATION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE CERTAIN RISKS AND UNCERTAINTIES. ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF VARIOUS RISKS AND UNCERTAINTIES, INCLUDING THOSE RISK FACTORS DISCUSSED IN THE ANNUAL AND QUARTERLY REPORTS THAT CYTRX FILES WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION.

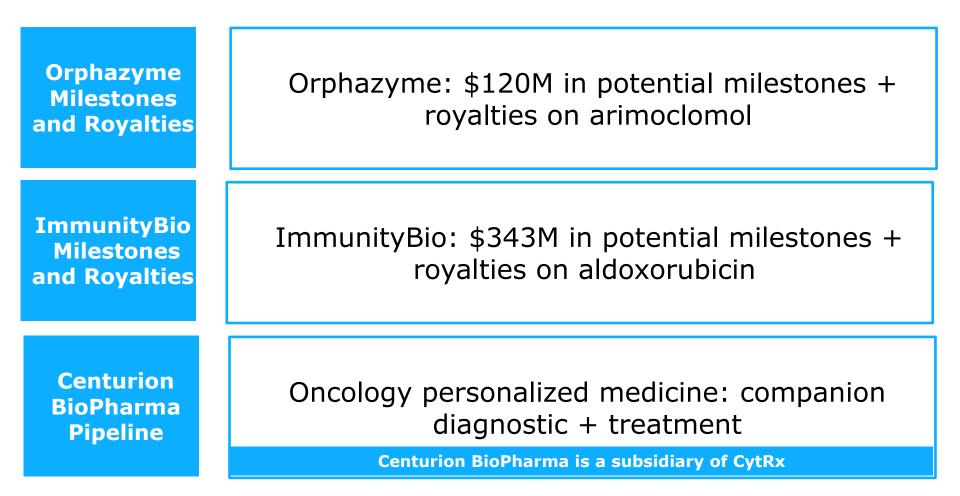


# **CytRx Highlights**

- CytRx's milestone and royalty agreement with Orphazyme for arimoclomol represents potential near term payments to CytRx
- Orphazyme prepares to file arimoclomol for approval with the FDA and EMEA authorities in 2020
- NantCell/ImmunityBio\* provided an update to its studies of aldoxorubicin in phase 1b/2 studies in combination with immunotherapy in multiple cancer indications, including a complete response in metastatic pancreatic cancer, at Bank of America Healthcare Conference
- Centurion BioPharma is a private oncology company focused on oncology treatment and has completed the pre-clinical phase for its ultra high potency LADR<sup>™</sup> drug candidates and accompanying albumin companion diagnostic (ACDx)



#### CytRx has potential milestone/royalty payments and a subsidiary called Centurion BioPharma





### CytRx may receive milestones and royalties from Orphazyme for Arimoclomol

Orphazyme Milestones and Royalties

Orphazyme: up to \$120M in milestones + royalties on arimoclomol

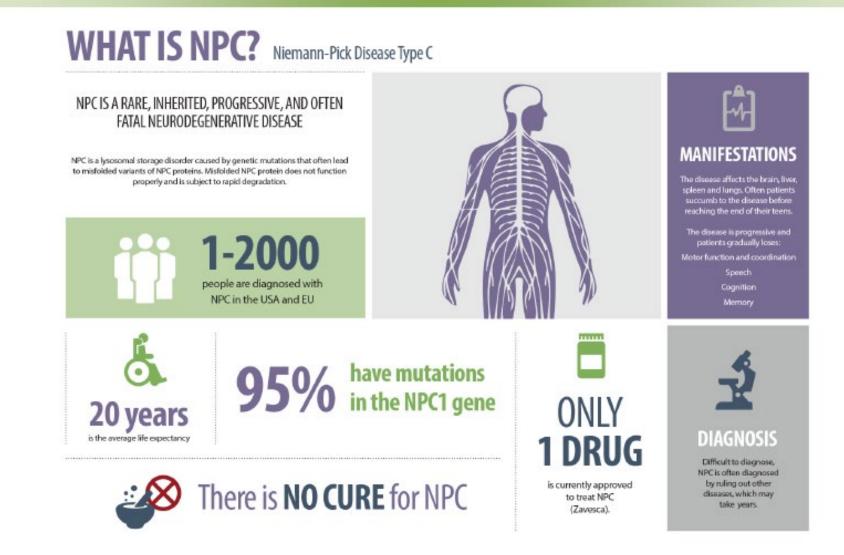
#### Niemann-Pick disease ("NPC")

- Orphazyme plans a regulatory filing with the FDA in H1 2020 and a regulatory filing with the EMA in H2 2020, both for arimoclomol for Niemann-Pick disease Type C (NPC).
- Orphazyme launched an Early Access Program for NPC in January 2020 to further accelerate access to treatment with arimoclomol for people living with NPC.
- Expected price range is \$300,000 \$600,000.
- Total worldwide patients numbering approximately 3,000.
- Go to market in US H1 2021 and EU/RoW H2 2021.



#### Niemann-Pick Disease Type C (NPC)





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#### Sporadic Inclusion Body Myositis (sIBM)

- Phase I 24 patient pilot trial results where 83% of arimoclomol treated patients were stabilized versus 25% on placebo. 4 months of continuous treatment resulted in a 60% reduction in progression, and at 8 months, there was a 75% reduction in progression.
- Phase II/III trial is fully enrolled. Study completion expected by end of 2020 Results are expected in H1 2021 and regulatory submission in H2 2021.
- Estimated 40,000 patients in US/EU.



### **Orphazyme – other indications**

#### **Amyotrophic Lateral Sclerosis (ALS)**

- Enrollment completed in P3 trial last July 2019.
- Fast Track Designation from the FDA received in May 2020.
- Announcement of P3 results in ALS in H1 2021.
- Regulatory submission in H2 2021.

#### **Gaucher Disease**

Announcement of results of P2 trial H1 2020

#### **Parkinson's Disease**

Commenced pre-clinical work with arimoclomol



### Orphazyme development programs for arimoclomol



\*Arimoclomol has been granted Rare Pediatric Disease Designation by the FDA for NPC, \*\*Glucocerebrosidase (GCase)



#### Source: www.orphazyme.com

### CytRx may receive milestones and royalties from ImmunityBio for aldoxorubicin

ImmunityBio Milestones and Royalties

ImmunityBio: up to \$343M in milestones + royalties on aldoxorubicin

- NantCell is now called ImmunityBio and is a privately held company involved in late stage clinical development
- ImmunityBio announces initiation of a phase 2 registrational-intent study using aldoxorubicin in combination with immunotherapy in metastatic pancreatic cancer
- Results from P1b study in TNBC presented at San Antonio Breast Cancer Symposium and at Bank of America Healthcare Conference
- Early safety and efficacy data from a portion of the studies was presented at Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting
- CytRx is entitled to increasing double-digit royalties on aldoxorubicin for soft tissue sarcomas and increasing single-digit royalties for all other indications



### CytRx partnered Pipeline with ImmunityBio - aldoxorubicin

Aldoxorubicin	Preclinical	Phase 1	Phase 2	Phase 3
2 <sup>nd</sup> -Line Soft Tissue Sarcoma	Ph 3 – Complete	ed; NantCell has IND		
2 <sup>nd</sup> -Line Small Cell Lung Cancer	Ph 2 – Fully enro	olled; NantCell has IN		
Combo with ifosfamide – STS	Ph 1b/2 – Nanto	Cell has IND		
Combination Trials with Immunotherapy				
Pancreatic Cancer	Ph 2 – Enrolling	5		
Squamous Cell Carcinoma	Ph 1b/2 – On-g	oing		
Triple-Negative Breast Cancer	Ph 1b/2 – On g	oing		
Colorectal Cancer	Ph 1b/2 – On g	oing		



#### Update from NantKwest/ImmunityBio at the Bank of America Healthcare Conference

#### Metastatic Pancreatic Cancer QUILT-88: IND Approved March 2020

- Initiation of a <u>Registrational-Intent</u> Phase 2 randomized, two-cohort, open-label study for first and second-line treatment of locally advanced or metastatic pancreatic cancer
- Received FDA authorization and will initially enroll 268 subjects across both cohorts. They
  indicated enrollment expected to begin in June 2020.



### Update from NantCell/ImmunityBio at the San Antonio Breast Cancer Symposium

#### Phase 1b Results in TNBC (triple negative breast cancer)

- In this Phase 1b, single-arm, open-label trial, treatment was administered in 3-week cycles of low-dose chemotherapy (aldoxorubicin, cyclophosphamide, cisplatin, nab-paclitaxel, 5-FU/L), antiangiogenic therapy (bevacizumab), engineered allogeneic high affinity CD-16 NK-92 cells (haNK), IL-15RaFc (N803), adenoviral vector-based CEA, MUC1, Brachyury, HER2 vaccine, yeast vector-based RAS, Brachyury and CEA vaccine, and an IgG1 PD-L1 inhibitor, avelumab plus cetuximab. All patients in both trials received aldoxorubicin. The primary endpoint is incidence of treatment-related adverse events (AEs). Secondary endpoints include overall response rate (ORR), disease control rate (DCR), progression-free survival (PFS), and overall survival (OS). This immunotherapy includes aldoxorubicin as part of its innovative chemoradiation therapy.
- The data highlights include of the nine patients treated efficacy results include a disease control rate of 78% (7/9 patients) and an overall response rate of 67% (6/9 patients). 2 out of 9 patients to date have ongoing complete responses with durations from 8 to 11 months, with a 3<sup>rd</sup> patient demonstrating a partial response (near complete response) in the target lesion after initiation of targeted and endocrine therapy off-study. To date, 7 patients are alive with durations of responses ranging from 2 to 12 months with 4 patients remaining on study. Median progression-free survival rate is 13.7 months. All patients were treated in an outpatient setting with treatment generally safe and well tolerated and no observed cytokine release syndrome.
- NantKwest indicated they plan to initiate a registration trial in TNBC.



### Update from NantCell/ImmunityBio at the J.P. Morgan Healthcare Conference in January 2020

#### <u>Complete Response in one Patient in its Phase 1b Trial in Metastatic Pancreatic</u> <u>Cancer</u>

- Based on the safety and efficacy of this Phase 1b in 11 patients who had received 3-week cycles of low-dose chemotherapy (aldoxorubicin, cyclophosphamide, oxaliplatin, nab-paclitaxel, 5-FU/L), antiangiogenic therapy (bevacizumab), engineered allogeneic high affinity CD-16 NK-92 cells (haNK), IL-15RaFc (N-803), adenoviral vector-based CEA vaccine, yeast vector-based RAS vaccine, and an IgG1 PDL1 inhibitor, avelumab, an expanded regime trial was authorized to study a patient with metastatic pancreatic cancer who had failed standard of care. After five infusions of this treatment, a complete response was confirmed. All metastatic pancreatic cancer patients received aldoxorubicin. The primary endpoint is incidence of treatment-related AEs. Secondary endpoints include ORR, DCR, PFS, and OS.
- It is expected that this patient's progress as well as report data from the full 11 metastatic pancreatic patients enrolled will be announced in 2020.
- NantKwest indicated they plan to initiate a registration trial in pancreatic cancer patients that failed standard of care.



### CytRx subsidiary Centurion BioPharma has an oncology preclinical pipeline

Centurion BioPharma Pipeline

Oncology personalized medicine: companion diagnostic + treatment

### LADR<sup>™</sup> (linker activated drug release) <u>albumin</u> binding drug conjugates

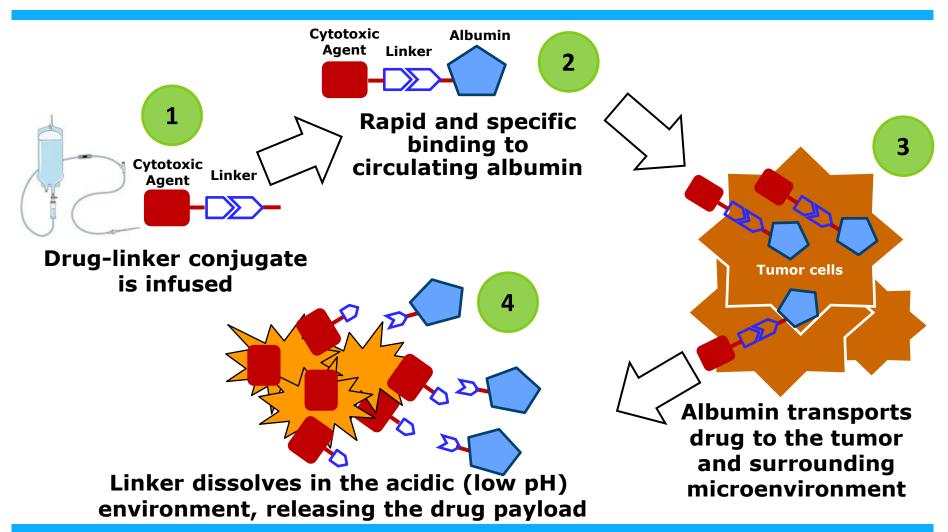
LADR-7 LADR-8 LADR-9 LADR-10

#### Albumin companion diagnostic (ACDx)

identifies tumors eligible for treatment with LADR<sup>™</sup>



### **LADR<sup>TM</sup>** Mechanism of Action





# **Recent and Upcoming Catalysts**

- ✓ 2020: Reduce cash burn rate to ~\$385,000 per month
- 1H 2020: Orphazyme to file for FDA approval for arimoclomol in Niemann-Pick Type C disease
- 2H 2020: Orphazyme to file for EMEA (Europe) approval for arimoclomol in Niemann-Pick Type C disease
- 2020-2021: Upon approval, CytRx is to receive a \$12 million milestone payment if the US, Europe and Japan are approved (\$6 million for US, \$4 million for Europe and \$2 million for Japan)
- 1H 2021: Orphazyme to announce top line results from the full analysis of phase 3 clinical trial of arimoclomol in amyotrophic lateral sclerosis (ALS)
- 1H 2021: Orphazyme to announce results of sIBM phase 2/3 clinical trial



# **Financial Summary**

<ul> <li>Cash Position (3/31/2020)</li> </ul>	\$15.3M
<ul> <li>No Debt</li> </ul>	
<ul> <li>Shares Outstanding</li> </ul>	33.6M
<ul> <li>Options Weighted-average strike price: \$3.32</li> </ul>	7.7M
<ul> <li>Warrants</li> </ul>	
<ul> <li>Weighted-average strike price: \$8.60</li> </ul>	0.2M
<ul> <li>Fully-Diluted Share Count (03/31/2020)</li> </ul>	41.5M



### Summary

- Orphazyme could deliver milestones + royalties
- ImmunityBio could deliver milestones + royalties
- Reduction in cash burn rate to ~\$385k per month
- Potential to selectively leverage our cash reserve for new business opportunities

