

# DURECT CORPORATION

## Corporate Factsheet, October 2020

DURECT is committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program.

### PIPELINE OVERVIEW

Indication	Phase 1	Phase 2	Phase 3	NDA	Status
<b>DUR-928 INJECTION</b> Alcoholic Hepatitis (AH)					Positive Phase 2a; Phase 2b initiation planned for Q4 2020
<b>EPIGENETIC REGULATOR PROGRAM</b> <b>DUR-928 INJECTION</b> COVID-19					Phase 2 in COVID-19 pts with acute kidney/liver injury
<b>DUR-928 ORAL</b> NASH					Positive Phase 1b topline results
<b>505(b)(2) PROGRAM</b> <b>POSIMIR®</b> Post-Operative Pain (bupivacaine extended-release solution)					FDA reviewing NDA

### FAST FACTS

NASDAQ: DRRX (Common Stock)

Cash & equivalents<sup>1</sup>: \$51.3 M

Debt<sup>1</sup>: \$20.5 M

Market Cap<sup>2</sup>: \$363 M

Shares outstanding<sup>1</sup>: 201 M

Avg Daily Volume<sup>3</sup>: 1.0 M

<sup>1</sup> as of 6/30/2020

<sup>2</sup> as of 10/15/2020

<sup>3</sup> 50 day average as of 10/15/2020

DUR  
928

DUR-928 is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival. It has been well-tolerated in completed trials, including nearly 300 subjects.

### PROGRAM HIGHLIGHTS

#### DUR-928 FOR ALCOHOLIC HEPATITIS: Compelling Opportunity in Underserved Market



Alcoholic hepatitis (AH): a life-threatening acute liver disease caused by chronic alcohol use with no approved drugs and a 28-day overall mortality rate of 26%; 117,000 US hospitalizations per year



Positive Phase 2a data: 100% survival rate demonstrated DUR-928's potential as a life-saving investigational therapy for AH



**Catalysts:** Phase 2b trial expected to begin 2H 2020; if robust survival benefit shown, may support NDA filing

#### DUR-928 FOR COVID-19 PATIENTS WITH ACUTE KIDNEY OR LIVER INJURY



In several publications, up to 60% of hospitalized COVID-19 patients have elevated liver enzymes and 36% had acute kidney injury. Liver and kidney injury are risk factors for poor outcomes in COVID-19 patients



**Catalysts:** Positive Phase 2 data would provide further compelling evidence of DUR-928's impact on acute organ injury; Successful therapeutics for COVID-19 may have an accelerated regulatory path

#### DUR-928 FOR NASH: Novel Approach via Epigenetic Regulation



Non-alcoholic steatohepatitis (NASH): most severe form of non-alcoholic fatty liver disease; no approved drugs



Positive top line Phase 1b data: significant improvements in liver enzymes, liver imaging and serum lipids



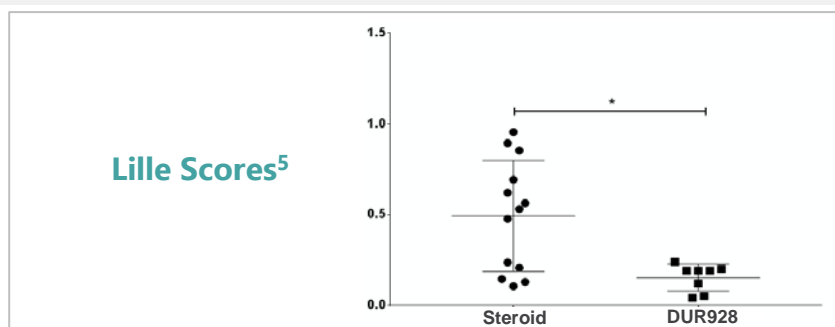
# DURECT CORPORATION

## Corporate Factsheet, October 2020

### DUR-928 FOR AH – COMPELLING PHASE 2A RESULTS

<b>Survival</b>	<b>100% of patients</b> treated with DUR-928 (n=19) survived the 28-day follow-up period in contrast to 26% historical 28-day mortality rate
<b>Time to Discharge</b>	<b>74% of patients treated with DUR-928 discharged within 4 days</b> or less of treatment after 1 dose
<b>Bilirubin</b>	<b>Significant reduction</b> compared to baseline at days 7 and 28
<b>Prognostic Indicators of Mortality for AH</b>	<p><b>MELD</b> (Model for End-Stage Liver Disease): significant reduction compared to baseline at day 28</p> <p><b>LILLE:</b> AH patients with Lille &lt;0.45 have an 85% 6-month survival rate vs. 25% survival rate when Lille &gt;0.45<sup>1</sup></p> <ul style="list-style-type: none"> <li>• <b>Lille response rate</b><sup>2</sup>: superior response rate (RR) in hospitalized AH patients for DUR-928: <b>89%</b><sup>3</sup> vs. standard of care: <b>53%</b><sup>4</sup></li> <li>• <b>Lille in severe AH patients:</b> significantly lower Lille scores in severe AH patients treated with 30mg or 90mg of DUR-928 vs. historical control of severe AH patients treated with steroids (shown below)<sup>5</sup></li> </ul>

<sup>1</sup> Louvet A et al. Hepatology 2007; 45: 1348-54. <sup>2</sup> Lille score <0.45 is considered a "responder." <sup>3</sup> Hassanein, et al. "Safety and Efficacy of DUR-928: A Potential New Therapy for Acute Alcoholic Hepatitis," Late-Breaking Presentation at AASLD The Liver Meeting® 2019, 11/12/2019. <sup>4</sup> Historical control from contemporaneous Univ. of Louisville study in 15 similar AH patients treated with standard of care. <sup>5</sup> McClain, et al., "DUR-928 Therapy for Acute Alcoholic Hepatitis: A Pilot Trial" AASLD The Liver Meeting® poster presentation, 11/10/2019.



### DUR-928 FOR NASH: POSITIVE 28-DAY PHASE 1B TOPLINE DATA

(N=65) \* Indicates p-value <0.05; \*\* indicates p < 0.01; \*\*\* indicates p <0.001

<b>Liver Enzymes</b>	Significant median <b>reduction</b> from baseline of serum <b>ALT</b> (-17%***), <b>AST</b> (-18%**), and <b>GGT</b> (-8%*) in the high dose group
<b>Liver Imaging</b>	At day 28, <b>43% of patients</b> showed <b>≥ 10% liver fat reduction</b> from baseline. <b>Significant reduction in liver stiffness</b> as measured by FibroScan (-10%**), in the low dose group
<b>Serum Lipid Profile</b>	Median <b>reduction in triglycerides</b> (-24%**), in patients with elevated baseline (≥200 mg/dL; n=16) across all dose groups; <b>Reduction in LDL-C</b> (-11%*) in the mid dose group

#### DURECT Forward-Looking Statements

The statements in this Corporate Fact Sheet regarding future events, including about DUR-928 and its potential to treat acute organ injury and chronic liver diseases, clinical trial plans and timing thereof, are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, our (and that of our third party collaborators where applicable) abilities to design, enroll, conduct and complete clinical trials, manufacture and commercialize DUR-928, manage and obtain capital to fund our operations and product development and ultimately obtain product approvals from regulatory agencies. Additional risks and uncertainties include future clinical trials of DUR-928 not being started when anticipated, taking longer to conduct than anticipated, not replicating the results from earlier clinical or pre-clinical trials, or not demonstrating the safety or efficacy of DUR-928 in a statistically significant manner and the risk that the FDA will not approve POSIMIR. Further information regarding these and other risks is included in our Form 10-Q filed for the period ended June 30, 2020 under the heading "Risk Factors" filed with the Securities and Exchange Commission.

### MANAGEMENT TEAM

James E. Brown, D.V.M.  
President and  
Chief Executive Officer

Michael H. Arenberg, J.D., MBA  
Chief Financial Officer

WeiQi Lin, M.D., Ph.D.  
Executive VP, R&D  
& Principal Scientist

Judy Joice  
Senior VP, Operations and  
Corporate Quality Assurance

### CONTACT

#### Corporate Headquarters

DURECT Corporation  
10260 Bubb Road  
Cupertino, CA 95014-4166  
Phone: 408-777-1417  
Fax: 408-777-3577  
www.durect.com

#### Investor Relations

Mike Arenberg, CFO  
Phone: 408-346-1052  
Email: mike.arenberg@durect.com

