Zacks Small-Cap Research

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Durect Corp (DRRX-NASDAQ)

DRRX: Zacks Company Report

DRRX: *Remoxy approved expected in 2H16, DUR-928 on track to enter into Phase II studies, Posimir Phase III initiated*

Current Price (07/29/16)	$1.94
Valuation	**$6.00**

OUTLOOK

Durect and its partner has resubmitted NDA for Remoxy and approval expected to be in 2H16. A new Phase III for Posimir is underway.

We are especially optimistic about the company's epigenomic regulator DUR-928, which holds great market potential for multiple indications, including NAFLD/NASH and acute kidney injury. Multiple Phase II trials will be initiated in late 2016 or early 2017.

We continue to be positive about the Durect story.

SUMMARY DATA

52-Week High	**$2.58**
52-Week Low	**$1.01**
One-Year Return (%)	**-17.45**
Beta	**1.01**
Average Daily Volume (sh)	**706,244**
Shares Outstanding (mil)	**137**
Market Capitalization ($mil)	**$266**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-20.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	4.8 A	4.4 A	4.7 A	5.2 A	19.1 A
2016	3.6 A	3.2 A	3.3 E	3.5 E	13.6 E
2017					30.7 E
2018					48.9 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.04 A	-$0.05 A	-$0.05 A	-$0.05 A	-$0.19 A
2016	-$0.06 A	-$0.07 A	-$0.06 E	-$0.07 E	-$0.26 E
2017					-$0.16 E
2018					-$0.05 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Update on Second Quarter Financials

On August 1, Durect (Nasdaq: DRRX) announced its financial results for the second quarter of 2016 ended June 30.

Total revenues for 2Q16 were $3.2 million, compared to $4.4 million for the same period of last year, a decrease of 28.8%.

R&D expenses for 2Q16 were $7.9 million, compared to $5.6 million for 2Q15.

SG&A expenses for 2Q16 were $2.9 million, compared to $2.7 million for 2Q15.

Net loss for the second quarter of 2016 was $9.0 million, as compared a net loss of $5.5 million for the three months ended June 30, 2015.

Considering Durect's current development stage, we think earnings report is a non-event for Durect. We recommend investors to be focused on the company's balance sheet and advancement the company has made for its pipeline. In this regard, we think Durect has made great progress during the first half of 2016.

Balance Sheet Remains Strong

As of June 30, 2016, Durect had cash and investments of $33.9 million, compared to cash and investments of $29.3 million at December 31, 2015. At June 30, 2016, the company had $19.8 million in short and long term debt.

In late April, 2016, Durect closed an underwritten public offering of 13,800,000 shares of its common stock, offered at a price of $1.25 per share to the public, including 1,800,000 shares purchased by the underwriters pursuant to their option. All of the shares in the offering were sold by DURECT. The gross proceeds to the company from this offering were approximately $17.3 million, before deducting underwriting discounts and commissions, and other estimated offering expenses.

In July 2016, Durect refinanced its existing $20 million term loan with Oxford Finance into a new term loan that results in an extended maturity (to four years) and an extended interest only period (to 18 months).

Current cash balance can last into the end of 2017 according to our financial model.

We welcome the new financing, which not only boosted the company's balance sheet, but more importantly validates the company's technology and clinical programs.

Update on Remoxy

In March 2016, Durect's licensee, Pain Therapeutics (PTIE), resubmitted the New Drug Application (NDA) for **REMOXY®** (oxycodone capsules CII) to the FDA. On April 12, 2016 the FDA accepted the NDA application.

A Prescription Drug User Fee Act (PDUFA) action date is set to be on September 25, 2016.

In May 2016, positive data from a REMOXY human abuse potential study was presented at the 35th Annual Scientific Meeting of the American Pain Society. Also in May 2016, the FDA informed Pain Therapeutics that there was a tentative date of August 5, 2016 for an Advisory Committee meeting to review the REMOXY NDA. In July 2016, Pain Therapeutics announced that the FDA had determined

that the Advisory Committee meeting is unnecessary and would not be held on August 5. Pain Therapeutics also stated that the FDA advised them that the regulatory review remains active and is on-going, and the PDUFA date of September 25, 2016 remains unchanged.

The original REMOXY NDA has a Priority Review Designation.

Based on DURECT's ORADUR®technology, REMOXY (oxycodone extended-release capsules) is a unique oral, long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse. REMOXY is designed to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

We expect REMOXY to be approved in 2H16 with a high probability.

Chronic pain affects as many as 100 million Americans annually. When chronic pain is severe enough, patients are frequently prescribed long-acting opioid analgesics. Opioids (also called narcotics) include oxycodone, hydrocodone, hydromorphone, oxymorphone, morphine, fentanyl, methadone, and other members of this class.

While opioids are effective at treating pain, they are also widely misused and abused. The FDA has recently described this situation as the opioid abuse epidemic, and called for a far-reaching action plan to reassess the agency's approach to opioid medications. One element of this action plan includes expanding access to, and encouraging the development of, abuse-deterrent formulations of opioid products.

The extended release oxycodone market is ~$2.4 billion in the U.S. alone. We believe that REMOXY represents a $500-750 million drug, of which Durect is entitled to 6-11.5% royalties on commercial sales once launched.

• US OxyContin® sales in 2014:	~$2.4 billion
• Blended royalties on net sales:	6% to 11.5%

Illustrative Royalty Calculations:
(in millions)

% of 2014 US OxyContin Sales	**10%**	**20%**	**30%**
REMOXY Annual Sales	$ 242	$ 484	$ 726
Royalties to DURECT *	**$ 16**	**$ 35**	**$ 55**

If approved, Remoxy would be the first pharmaceutical product in Durect's pipeline authorized for commercialization.

Update on Posimir (SABER®-Bupivacaine) Post-Operative Pain Relief Depot

In November 2015, Durect began enrolling patients for PERSIST, the POSIMIR pivotal **Phase III** clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. The company began recruiting patients for this trial comparing POSIMIR to placebo. Based on recommendations from the FDA received subsequent to the start of the trial, in April 2016 Durect decided to amend the PERSIST trial. Starting in August 2016, the company is implementing Part 2 of the PERSIST trial to evaluate POSIMIR against standard bupivacaine HCl rather than placebo as the company has been doing in Part 1.

Additionally, the company is switching in Part 2 the primary efficacy endpoint (pain reduction on movement) from 0-72 hours after surgery to 0-48 hours after surgery. Assessing pain reduction on movement from 0-72 hours is now the key secondary efficacy endpoint and other efficacy endpoints, including 72-hour opioid use, remain the same. Durect expects to enroll approximately **264 patients** in Part 2 of PERSIST, and expects this part of the trial to take approximately one year to enroll.

This change will add to the time and cost to complete the PERSIST trial, but we believe that a positive outcome from this trial design would result in a stronger NDA filing and potentially provide commercial advantages.

In a previous clinical trial of 50 patients in the same surgical model (laparoscopic cholecystectomy), POSIMIR was compared with the active control bupivacaine HCl, against which POSIMIR demonstrated in a post hoc analysis an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.024) and for the first 2 days after surgery (p=0.0198), using the same statistical methodology specified for the current trial.

POSIMIR is the company's investigational post-operative pain relief depot that utilizes the company's patented SABER technology and is intended to deliver bupivacaine to provide 3 days of pain relief after surgery. The company is in discussions with potential partners regarding licensing development and commercialization rights to POSIMIR, for which Durect holds worldwide rights. The company is also continuing to evaluate the requirements for commercializing POSIMIR on its own in the U.S., in the event that the company determines that to be the preferred route of commercialization.

Update on ORADUR-ADHA Program

In 2013, Durect selected a formulation for the lead program in its ORADUR-ADHD program, ORADUR-Methylphenidate. This formulation was chosen based on its potential for rapid onset of action, long duration with once-a-day dosing and target pharmacokinetic profile as demonstrated in a Phase I trial.

In addition, this product candidate utilizes a small capsule size relative to the leading existing long acting products on the market and incorporates the company's ORADUR anti-tampering technology. Orient Pharma, the company's licensee in defined Asian and South Pacific countries, has initiated a **Phase III** study in Taiwan and anticipates completing it in 2016.

Durect retains rights to all other markets in the world, notably including the U.S., Europe and Japan, and is engaged in licensing discussions with other companies.

Phase Ib Oral Study of DUR-928 for NASH Initiated

In January, 2016, Durect initiated a single-ascending-dose **Phase Ib** clinical trial with oral DUR-928 in patients with nonalcoholic steatohepatitis **(NASH).**

This Phase Ib trial of DUR-928 is a dose ranging, single-ascending-dose safety and pharmacokinetic study of DUR-928 of subjects with NASH and matched control subjects. This study will be conducted in three successive cohorts evaluating three single-dose levels of oral DUR-928. After a PK/safety review at each dose, the study can proceed to a successively higher dose. Assuming all three cohorts are dosed, the study will comprise approximately 48 subjects, of which approximately 30 will have received DUR-928.

The study is being conducted in Australia and the company anticipates to collect data in the **third quarter of 2016.** This study is designed to enable and inform a subsequent multi-dose study in NASH and/or other patients with other liver function impairment. The company is also preparing to request in the near future a pre-IND meeting with the FDA as precursor to submitting an IND **later this year** which is required to enable future clinical trials in liver diseases in the U.S.

The Phase Ib NASH patient trial is based on the positive **Phase I** safety data the company recently completed with the **oral formulation** of DUR-928.

The initial Phase I trial of DUR-928 was a single-site, randomized, double-blinded, placebo-controlled, **single-ascending-dose** study that evaluated the safety, tolerability and pharmacokinetics of DUR-928 when **orally administered** in 30 subjects. After the completion of the initial single-dose trial, the company subsequently conducted a Phase I **multiple-ascending-dose**, oral administration trial in 20 healthy subjects, evaluating DUR-928 in two consecutive 10-subject cohorts, the first receiving DUR-928 at a lower dose and the second at a higher dose.

In both Phase I clinical trials, DUR-928 was well-tolerated at all dose levels, with no clinically significant changes in vital signs, laboratory values or ECG parameters, no severe or serious drug-related adverse events reported and no subjects withdrawing from the study. Peak plasma concentrations achieved were at least 100-fold higher than endogenous levels, no accumulation in plasma concentrations were observed with repeat dosing, and dose related increases in plasma concentrations were observed with peak plasma concentration at approximately 2 – 6 hours after dosing.

A New Phase Ib with Injectable DUR-928 for Kidney Disease will be Initiated Soon

A second patient study with DUR-928, also being conducted in Australia, is currently screening patients with dosing expected shortly.

This new **Phase Ib** trial of DUR-928 is an open-label single-ascending-dose safety and pharmacokinetic study in patients **with impaired kidney function** and matched control subjects. This study will be conducted in successive cohorts evaluating single-dose levels of DUR-928 administered **by injection.**

After a PK/safety review at each dose, the study can proceed to a higher dose. The company anticipates that this study will be completed in 2016, and that this study will enable and inform subsequent trials for patients with **either acute kidney injury** or **other kidney function impairment**. A request for a pre-IND meeting has been granted by the FDA. The company anticipates that feedback from that meeting will enable the filing of an **IND later in the year** which is required to enable future clinical trials in kidney diseases in the U.S.

Positive Phase I Data for Injectable DUR-928 Announced

On Jan 6, 2016, Durect announced the successful completion of a **Phase I** clinical trial with an **injectable formulation** of DUR-928 intended for acute use indications.

The Phase I trial of injectable DUR-928 was a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of 4 doses of DUR-928 when administered through an intramuscular injection. Total of **24 healthy volunteers** in four cohorts were enrolled in the study with 16 receiving DUR-928 and 8 receiving placebo.

Peak plasma concentrations were over 100 fold higher than endogenous levels. DUR-928 was well-tolerated at all dose levels, with no treatment-related adverse events reported and plasma levels were dose proportional.

Before the highest dose was added to the single-ascending-dose study, the company proceeded to a multi-dose cohort including **10 healthy volunteers**, in which study participants received DUR-928 for 5 consecutive days (n = 8 on drug, 2 on placebo) with what at the time was the highest dose in the prior study. No treatment related adverse events were reported, no subjects withdrew from the study, no accumulation in plasma concentrations were observed with repeat dosing, and the pain scores and injection site reactions were minimal.

Following the completion of the Phase I trial, the company's protocol for **Phase Ib injectable DUR-928** has been approved by the institutional review board. This Phase Ib trial will also be conducted in Australia, which is an open-label single-ascending-dose safety and pharmacokinetic study in patients with impaired kidney function and matched control subjects. This study will be conducted in successive cohorts evaluating single-dose levels of DUR-928 administered **by injection**. After a PK/safety review at each dose, the study can proceed to the next higher dose.

Durect anticipates that this study to be completed in 2016, and that this study will enable and inform subsequent trials for patients with either acute kidney injury or other kidney function impairment.

What's next for DUR-928?

Durect plans to move into **Phase II** trial in late 2016 or early 2017 for both oral DUR-928 and injectable DUR-928, which will be conducted in Australia.

For oral DUR-928, the company plans to conduct **Phase IIa** multi-dose POC study in **NASH patients** if the Phase Ib data prove to be positive.

For injectable DUR-928, if data from the Phase Ib trial of injectable DUR-928 are positive, the company will conduct **Phase IIa** POC study in acute kidney injury and/or chronic kidney injury patients.

Long term opportunities fall into four broad categories:

- orphan acute indications;
- broader acute indications;
- orphan chronic indications, and
- broader chronic indications.

DURECT's initial Phase II studies will be designed to show an efficacy signal in patients suffering from one orphan acute condition such as acute **kidney injury** and one broad chronic indication such as **NAFLD/NASH**. We will provide update when the company provides more detail on the Phase II studies in the future.

DUR-928 Holds Great Potential for Multiple Indications

Among Durect's multiple candidates, DUR-928 may be the most promising one in our view because this compound has the potential to target multiple indications including NAFLD/NASH and acute kidney injury.

The Background

DUR-928 came from DURECT's Epigenomic Regulator Program, which is a collaborative effort between DURECT and the Department of Internal Medicine at Virginia Commonwealth University (VCU), the VCU Medical Center, and the McGuire VA Medical Center. During the course of this program, a number of compounds that may have therapeutic utility have been identified, including the lead molecule DUR-928. DURECT holds the exclusive worldwide right to develop and commercialize DUR-928 and related molecules discovered in the program.

DUR-928 is an endogenous (produced naturally by the body), orally bioavailable small molecule that modulates the activity of several nuclear receptors that play an important regulatory role in lipid homeostasis, inflammation and cell survival. Studies have showed that DUR-928 modulates the activity of more than 240 genes, including ACC, FAS, HMGR, Cyp7A1, LXR, PPARγ, NFκB/IκB, TNFα, IL-1α, IL-6, COX-2, PCSK9, and others.

The broad biologic activities indicate that DUR-925 may have a broad range of clinical applications including acute organ injury, ischemia or reperfusion injury, and chronic liver disease such as non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

Compelling Animal Data

Durect has completed **multiple animal studies** with compelling efficacy and safety data. These studies involved 7 different animal models involving three animal species.

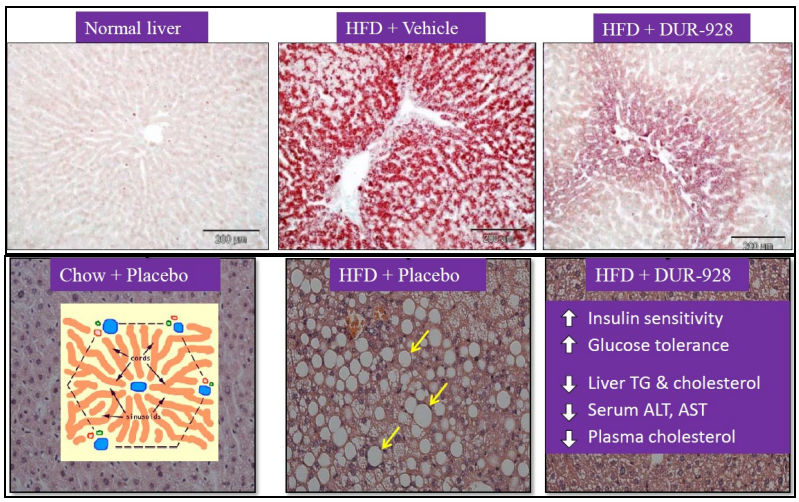
Four of these models represent **acute organ injury**, which include:

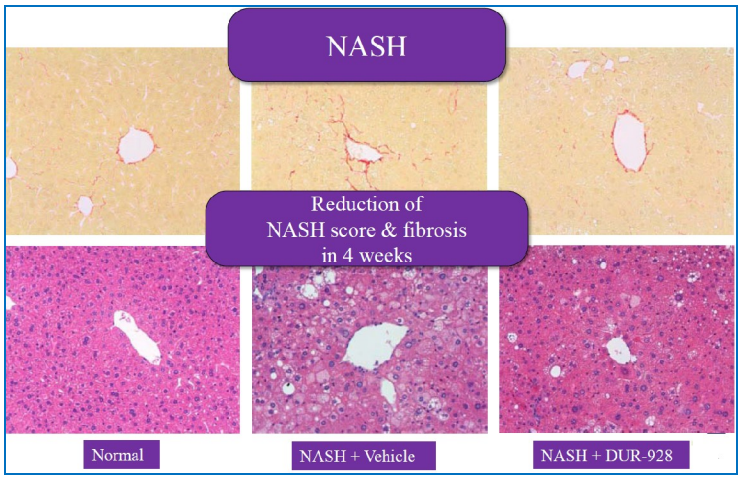
- liver toxicity mouse;
- endotoxin induced septic shock mouse;
- renal ischemia/reperfusion rat; and
- brain ischemia/stroke rat;

Three represent **chronic disorder animal models**. They are:

- high fat diet mouse;
- high fat diet hamster; and
- nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) mouse.

In the three chronic disorder animal models, DUR-928 treatment led to significant improvement in liver morphology and improvement in NAFLD/NASH score and fibrosis.

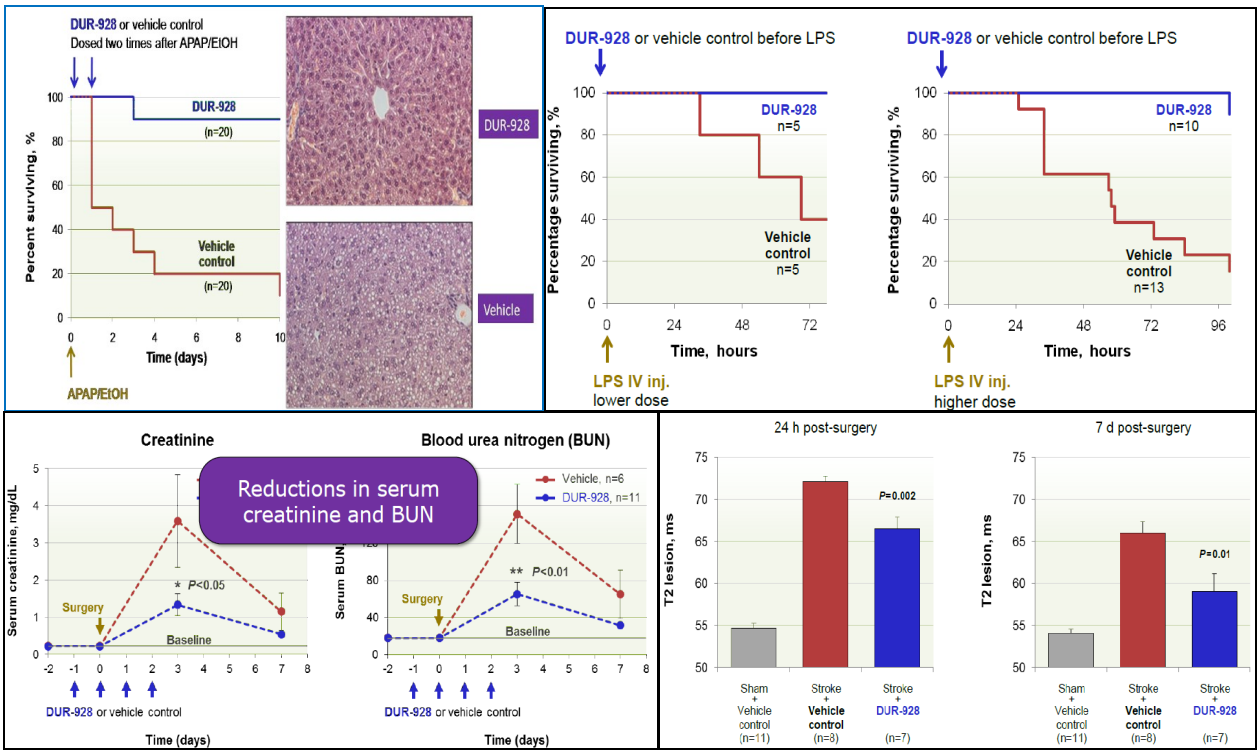




Top three panels represent the high fat diet mouse model. Middle three panels represent high fat diet hamster model. The bottom six panels represent NAFLD/NASH mouse model.

In all four acute organ injury models, DUR-928 treatment led significant increase in survival.

- In a chemical induced mouse liver toxicity model (upper left panel), 90% mice lived in the DUR-928 group while 90% mice died on the vehicle group.
- In an endotoxin-induced septic shock mouse model (upper right panel), 90-100% mice survived on the DUR-928 group, while only 15-40% mice lived on the vehicle group.
- In an acute kidney injury rat model (lower left panel), DUR-928 significantly reduced creatinine and blood urea nitrogen (BUN) in serum, indicating the organ protection by DUR-928.
- In a brain injury rat model (lower right panel), DUR-928 significantly reduced the T2 lesion (measure of cell viability).



Animal pharmacokinetics and toxicity studies have shown DUR-928 to be orally bioavailable and safe at all doses tested to date.

An injectable formulation, envisioned for use in acute conditions, is currently undergoing animal testing. The company plans to use the oral version of DUR-928 for chronic use and the injectable DUR-928 for acute use.

Large Market Opportunity for DUR-928

Although DUR-928 may have broad applications in many indications, we believe the initial focus will be in **NAFLD/NASH** and acute **kidney injury**.

Non-alcoholic fatty liver disease (NAFLD) is the build-up of extra fat in liver cells that is not caused by alcohol. It is normal for the liver to contain some fat. However, if more than 5% - 10% percent of the

liver's weight is fat, then it is called a fatty liver (steatosis). The more severe form of NAFLD is called non-alcoholic steatohepatitis (NASH). NASH causes the liver to swell and become damaged.

NAFLD affects about 30% of adults and 10% of children in the US, among which 10-30% will develop NASH. 25-40% NASH patients will develop progressive liver fibrosis, while 20-30% NASH patients with advanced fibrosis will develop cirrhosis, which could lead to liver cancer.

Currently there are no FDA approved medicines for the treatment of NAFLD/NASH.

Acute kidney injury (AKI) is defined as an abrupt or rapid decline in renal filtration function. This condition is usually marked by a rise in serum creatinine concentration or by azotemia (a rise in blood urea nitrogen [BUN] concentration).

According to Medscape, in the United States, approximately 1% of patients admitted to hospitals have AKI at the time of admission. The estimated incidence rate of AKI during hospitalization is 2-5%. AKI develops within 30 days postoperatively in approximately 1% of general surgery cases and arises in up to 67% of intensive care unit (ICU) patients. Approximately 95% of consultations with nephrologists are related to AKI. The appropriate nephrologist referral rate is approximately 70 cases per million populations.

The current treatment for AKI is mainly supportive in nature. No therapeutic modalities to date have shown efficacy in treating the condition. Therapeutic agents (eg, dopamine, nesiritide, fenoldopam, mannitol) are not indicated in the management of AKI and may be harmful for the patient.

Certainly there are highly unmet medical needs in the NAFLD/NASH and acute kidney injury fields. The unique mechanism of action and the compelling animal and human data so far make DUR-928 a highly promising candidate for the management of NAFLD/NASH and kidney injury.

Attractive Valuation

We continue to be optimistic about Durect story and reiterate our price target of $6.00 per share based on the progress the company has made in advancing its candidates.

Durect is a late development stage biotech company. Its two Phase III candidates are Posimir and Remoxy. The company and its partner Pain Therapeutics already resubmitted a NAD for Remoxy and we expect the drug to be approved by 2H2016.

The company has initiated a new Phase III PERSIST trial with its clinical candidate Posimir. We estimate top line data will be available in 1Q17 and the FDA approval will take place in late 2017 or early 2018. Following table summarizes the catalysts in the next 12-25 months.

Next 12 months	Next 24 months
• Potential for 1st product approval (REMOXY®)	• 1st product launched (REMOXY®)
• Initial patient data and start of Phase 2 (DUR-928)	• Phase 2 data in one or more indications (DUR-928)
• Enrolling Phase 3 (POSIMIR®)	• POSIMIR® resubmitted
• 1 new meaningful collaboration	• At least 1 new meaningful collaboration
• Phase 3 data in Taiwan (ORADUR®-Methylphenidate)	• Phase 3 in Europe/US (ORADUR®-Methylphenidate)

Based on our financial model, we expect the company will become profitable in 2019 with an EPS of $0.01 based on total revenue of $64 million, which include royalty revenue from Posimir and Remoxy, existing product sales and collaborative revenue. EPS will increase to $0.18 in 2020 based on total revenue of $96 million. Based on this model, we come up with a fair value of the company at $3.00 per share, which values the company at $405 million in market cap.

But remember this valuation only considers the company's existing products and the two late stage candidates of Remoxy and Posimir. As we discussed above, among the company's multiple candidates, we are especially optimistic about the company's epigenomic regulator program **DUR-928**, which holds great potential for multiple indications, such as NASH and acute kidney injury. Based on probability adjusted NPV analysis, we have a fair value of $3 for DUR-928.

We believe even with the only NAFLD/NASH indication, the market is big enough for DUR-928 to support the company's long term growth and valuation. If we look at the valuation of similar companies, we will have some sense how DUR-928 will impact Durect's valuation. We notice that three companies have similar NASH programs. ICPT and RPTP's NASH programs are in Phase II and FGEN's is in Phase I/II. Our $3.00 per share values Durect's DUR-928 program at $405 million in market cap based on 135 million outstanding shares, which is still conservative compared to its peers in our view.

Together our fair value for Durect is $6.00 per share, which values the company at $810 million in market cap. If the company can show positive DUR-928 data for NASH and/or acute kidney injury in the planned Phase II trials, share price can easily double.

Company	*Ticker*	*NASH stage*	*Current Share Price*	*Market Cap ($billion)*
Intercept Pharmaceuticals	ICPT	Phase II	$169.72	$4.18
FibroGen, Inc.	FGEN	Phase I/II	$19.73	$1.23
Raptor Pharmaceuticals	RPTP	Phase II	$6.07	$0.52
Average			**$65.17**	**$1.98**
DURECT Corporation	DRRX	Phase I/II	$1.90	$0.26

Source: Zacks Investment Research

PROJECTED INCOME STATEMENT & BALANCE SHEET

DURECT Corp	Q1A	Q2A	Q3A	Q4A	2015 A	Q1	Q2	Q3	Q4	2016 E	2017 E	2018 E	2019 E	2020 E
Posimir (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5	$12	$32
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*161.9%*
Remoxy (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$9.7	$22.4	$28.9	$40.3
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*131.4%*	*28.8%*	*39.7%*
DUR-928	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Alzet Pumps & Lactel Polymers	$3.0	$2.7	$2.7	$2.9	$11.3	$3.2	$2.8	$2.9	$3.1	$12.0	$11.5	$11.5	$11.5	$11.5
YOY Growth	*9.1%*	*-6.4%*	*7.4%*	*-3.6%*	*1.3%*	*5.1%*	*4.6%*	*7.8%*	*6.8%*	*6.0%*	*-4.0%*	*0.0%*	*0.0%*	*0.0%*
Collaborative Revenue	$1.7	$1.8	$2.1	$2.3	$7.8	$0.4	$0.4	$0.4	$0.4	$1.6	$9.5	$10.0	$11.0	$12.0
YOY Growth	*-50.5%*	*2.5%*	*17.1%*	*80.1%*	*-5.1%*	*-75.9%*	*-79.1%*	*-80.5%*	*-82.3%*	*-79.7%*	*497.5%*	*5.3%*	*10.0%*	*9.1%*
Total Revenues	**$4.8**	**$4.4**	**$4.7**	**$5.2**	**$19.1**	**$3.6**	**$3.2**	**$3.3**	**$3.5**	**$13.6**	**$30.7**	**$48.9**	**$63.6**	**$95.9**
YOY Growth	*-24.2%*	*-3.1%*	*11.4%*	*21.0%*	*-1.4%*	*-24.4%*	*-28.3%*	*-30.4%*	*-32.3%*	*-29.1%*	*126.2%*	*59.4%*	*30.1%*	*50.8%*
Cost of Goods Sold	$1.0	$1.0	$0.9	$1.0	$3.9	$1.2	$0.9	$1.0	$1.1	$4.2	$4.8	$5.0	$5.2	$5.5
Product Gross Margin	*66.9%*	*61.6%*	*67.1%*	*65.8%*	*65.4%*	*61.1%*	*67.2%*	*65.0%*	*65.0%*	*65.0%*	*58.3%*	*56.5%*	*54.8%*	*52.2%*
SG&A	$2.8	$2.7	$3.2	$2.8	$11.6	$3.1	$2.9	$3.0	$3.1	$12.1	$14.0	$15.0	$16.0	$18.0
% SG&A	*59.1%*	*61.3%*	*67.0%*	*55.1%*	*60.5%*	*84.3%*	*91.5%*	*90.3%*	*88.6%*	*88.8%*	*45.6%*	*30.7%*	*25.1%*	*18.8%*
R&D	$5.4	$5.6	$6.7	$6.7	$24.3	$6.6	$7.9	$7.5	$8.0	$30.0	$32.0	$35.0	$40.0	$45.0
% R&D	*112.4%*	*127.0%*	*140.3%*	*128.9%*	*127.2%*	*183.6%*	*248.7%*	*227.3%*	*228.6%*	*221.0%*	*104.3%*	*71.6%*	*62.9%*	*46.9%*
Operating Income	($4.4)	($4.9)	($6.0)	($5.3)	($20.7)	($7.3)	($8.5)	($8.2)	($8.7)	($32.7)	($20.1)	($6.1)	$2.4	$27.4
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*-12.4%*	*3.8%*	*28.6%*
Interest & Other Net	($0.4)	($0.5)	($0.5)	($0.5)	($2.0)	($0.5)	($0.5)	($0.5)	($0.5)	($2.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	($4.9)	($5.5)	($6.5)	($5.8)	($22.7)	($7.9)	($9.0)	($8.7)	($9.2)	($34.7)	($21.1)	($7.1)	$1.4	$26.4
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($4.9)	($5.5)	($6.5)	($5.8)	($22.7)	($7.9)	($9.0)	($8.7)	($9.2)	($34.7)	($21.1)	($7.1)	$1.4	$26.4
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*-120.1%*	*1756.3%*
Reported EPS	($0.04)	($0.05)	($0.05)	($0.05)	($0.19)	($0.06)	($0.07)	($0.06)	($0.07)	($0.26)	($0.16)	($0.05)	$0.01	$0.18
YOY Growth	-	-	-	-	-					-	-	-	-	-
Shares Outstanding	113.8	118.8	120.5	120.5	118.5	122.1	132.8	136.0	137.0	132.0	135.0	140.0	145.0	150.0

Source: company filings and Zacks estimates

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