Zacks Small-Cap Research

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Durect Corp (DRRX-NASDAQ)

DRRX: Zacks Company Report

DRRX: *DUR-928 on track to enter into Phase II studies, and holds great potential for long term growth*

Current Price (10/31/16)	$1.12
Valuation	**$6.00**

OUTLOOK

Durect is a late stage biotech company with Remoxy approval expected to be in late 2017 or early 2018. 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	**$2.54**
52-Week Low	**$1.01**
One-Year Return (%)	**-45.10**
Beta	**0.96**
Average Daily Volume (sh)	**420,302**
Shares Outstanding (mil)	**137**
Market Capitalization ($mil)	**$154**
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	3.7 A	3.5 E	14.0 E
2017					26.0 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 A	-$0.07 E	-$0.25 E
2017					-$0.19 E
2018					-$0.05 E

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

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WHAT'S NEW

Durect Exited Third Quarter with Strong Balance Sheet

On October 31, Durect (Nasdaq: DRRX) announced its financial results for the third quarter of 2016 ended September 30.

Total revenue for 3Q16 was $3.7 million, compared to $4.7 million for the same period of last year, a decrease of 21%.

Product sales were $3.4 million for 3Q16, compared to $2.7 million for 3Q15, an increase of 26%. Removing the one-time charge of $0.9 million, gross margin for product sales remained at 61%.

Collaborative R&D revenue was $0.4 million for 3Q16, compared to $2.1 million for 3Q15.

R&D expenses for 3Q16 were $6.8 million, compared to $6.7 million for 3Q15.

SG&A expenses for 3Q16 were $3.0 million, compared to $3.2 million for 3Q15.

Net loss for the third quarter of 2016 was $8.8 million, as compared a net loss of $6.5 million for the three months ended September 30, 2015.

As of September 30, 2016, Durect had cash and investments of $27.8 million. At September 30, 2016, the company had $19.8 million in long term debt.

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.

Update on Remoxy

In September 2016, Durect's licensee, Pain Therapeutics, received a Complete Response Letter (CRL) from the FDA for REMOXY ER. Based on its review, the FDA has determined that the NDA cannot be approved in its present form and specifies additional actions and data that are needed for final approval.

According to Pain Therapeutics, the CRL focused on the abuse-deterrent properties of REMOXY ER and proposed drug labeling. The CRL made no mention of clinical safety, drug efficacy, manufacturing, stability, bioequivalence or any other issues from a prior Complete Response Letter.

The CRL specified additional actions that are needed in order to obtain approval of REMOXY ER with label claims against three routes of abuse (i.e., injection, inhalation and snorting).

Specifically, Pain Therapeutics need to conduct the following studies, comparing REMOXY ER vs. one or more commercially available oxycodone ER drug product:

- **To support a potential drug label claim against abuse by injection:** Repeat an injectability/syringeability study using thin films of drug, smaller volumes of solvents, additional mixed solvents and alternative extraction methods and syringe filter.
- **To support a potential drug label claim against abuse by inhalation:** Repeat a volatilization study using the same thickness for each drug to increase surface area.
- **To support a potential drug label claim against abuse by snorting:** Conduct an intranasal abuse potential study in human volunteers (i.e., not the animal data we had submitted) with drug applied directly inside the human nasal cavity.

These actions may take approximately a year to conduct and may cost approximately $5 million.

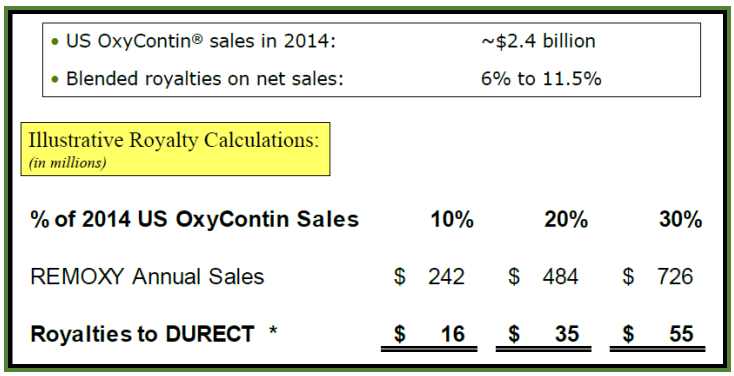
Pain Therapeutics is evaluating the comments raised by the FDA and is consulting with outside experts.

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.

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 the company expects this part of the trial to finish dosing patients in the third quarter of 2017.

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, 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.

Update on DUR-928 Programs

As Durect's Epigenetic Regulator Program's lead product candidate, **DUR-928** is an endogenous, small molecule, new chemical entity (NCE), which may have broad applicability in several metabolic diseases such as nonalcoholic steatohepatitis (NASH), and in acute organ injuries such as acute kidney injury. As we stated in our previous reports, we think DUR-928 is the most important program for Durect and the key value driver for the company in the long run.

Phase Ib Oral Study of DUR-928 for NASH

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

This Phase Ib trial of DUR-928 is a dose ranging, single-ascending-dose safety and pharmacokinetic study of oral DUR-928 in 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 company has completed the **first, low dose, cohort**, consisted of 10 subjects with NASH (of which 4 were cirrhotic and 6 were not cirrhotic) and 6 matched control subjects. After a PK/safety review of this cohort, the study has proceeded to the higher dose cohort utilizing a dose four times larger than the low dose cohort. Major findings from the first cohort:

- Data from the first cohort showed the PK parameters between the NASH patients and the matched control subjects were comparable.

- While this study was not designed to assess the efficacy of DUR-928, certain clinical chemistry biomarkers for liver function and liver injury were reduced 12 hours after dosing with DUR-928 as compared to before dosing.

- Furthermore, high sensitivity C-Reactive Protein (hsCRP), a marker of inflammation, was reduced after dosing with DUR-928. IL-18, an inflammatory mediator implicated in both liver and kidney diseases, decreased in the NASH patients as soon as a few hours after dosing, with the effect more pronounced in cirrhotic subjects at 12 hours after dosing; there was little or no change of IL-18 levels in matched control subjects.

- In addition, both full length CK18 (a generalized cell death marker) and cleaved CK18 (a cell apoptosis marker) were reduced after DUR-928 treatment in the NASH patients, with the effect more pronounced in cirrhotic subjects, and little or no change in matched control subjects.

These preliminary results from the low dose cohort are especially encouraging in our view. Collectively, the reduction of these biomarkers plus results from the company's animal and cell culture studies suggest potential therapeutic activity of DUR-928 for patients with liver disease.

The trial is currently enrolling and dosing patients in the higher dose cohort, which is expected to complete **in 2016.** This single-ascending-dose Phase Ib trial will enable and inform future studies in patients with liver diseases. Durect has requested a pre-IND meeting with the FDA with respect to a future liver disease clinical trial **in the United States**.

Phase Ib Injectable DUR-928 for Kidney Disease

This ongoing trial is also conducted in **Australia**.

This **Phase Ib** trial of DUR-928 is an open-label single-ascending-dose safety and pharmacokinetic study in patients **with impaired kidney function** (stage 3 and 4 chronic kidney disease) 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 of the low dose, the study can proceed to a higher dose. Assuming both cohorts are dosed, the study will comprise approximately 16-18 subjects, of which approximately 10-12 will have received DUR-928. 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**.

The company recently held a pre-IND meeting with the Cardiovascular and Renal Products Division of the FDA and plans to file an IND which is required to enable a future kidney disease clinical trial in the United States.

Results from additional animal studies

During the third quarter earnings conference call, management of Durect also discussed two additional animal disease models.

In a **mouse model** of advanced NASH conducted by a Contract Research Organization (CRO) in Japan, the treatment was initiated after fibrosis had formed and stopped after nodules had developed. Daily oral administration of DUR-928 for 4 weeks resulted in statistically significant reduction of fibrosis and hepatocyte ballooning as compared to placebo control. The fibrosis seen at the end of the study in DUR-928 treated animals was less than that seen at the beginning of the treatment. The hepatocyte ballooning seen at the end of the study in the DUR-928 group was significantly lower than at the beginning of the treatment.

In a bile duct ligation rat model (a model for cholestatic liver diseases such as Primary Sclerosing Cholangitis or **PSC**) conducted by a CRO in Canada, the bile duct was surgically ligated, resulting in cholestatic inflammatory liver injury. Daily oral administration for nine days of DUR-928 showed significant improvement in body temperature and body weight, as well as a statistically significant reduction of total bilirubin (including both direct and indirect bilirubin).

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.

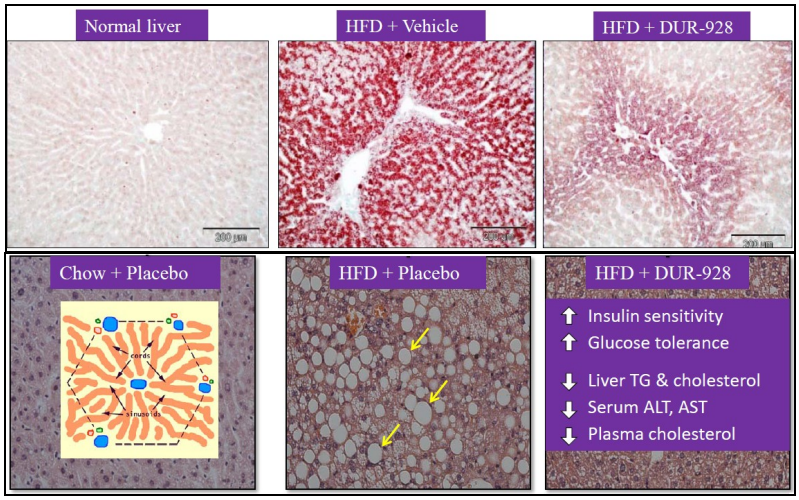
Four of these models represent **acute organ injury**, which include:

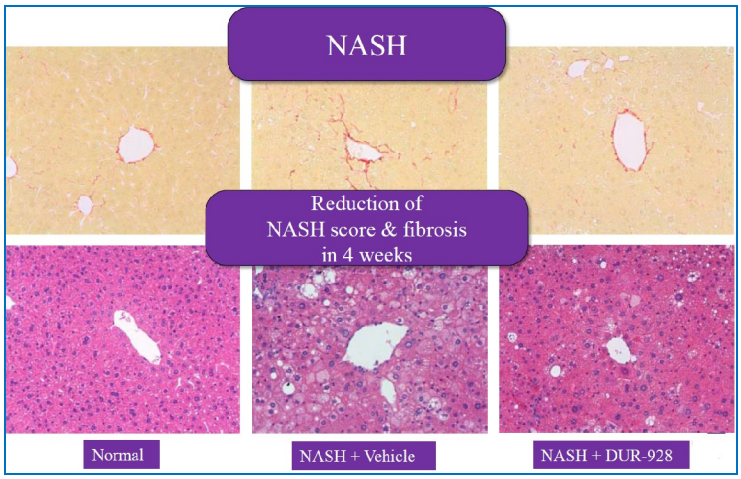
- liver toxicity mouse;
- endotoxin induced septic shock mouse;
- renal ischemia/reperfusion rat; and
- brain ischemia/stroke rat;

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.

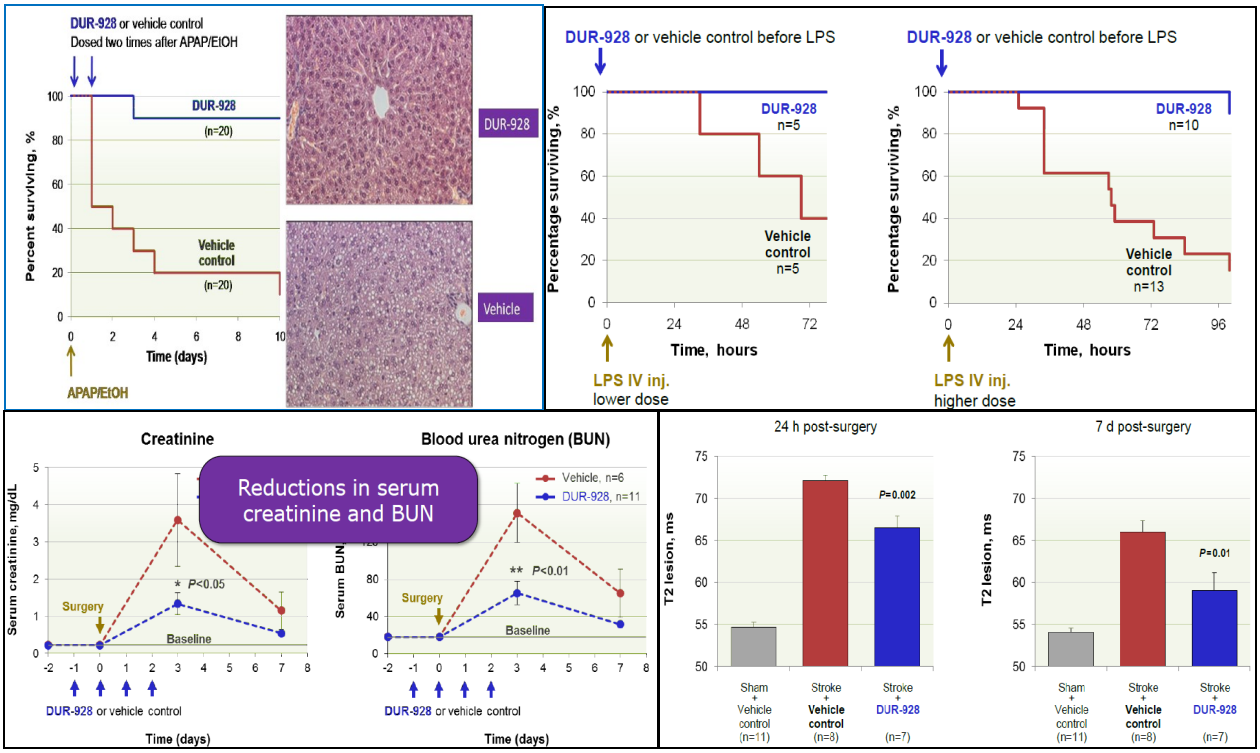




Top three panels represent the high fat diet mouse model. Middle three panels represent high fat diet hamster model. The bottom six panels represent NAFLD/NASH mouse model.

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. Although Remoxy received a CRL from the FDA, we still believe this is a viable program and will be approved in late 2017 or early 2018.

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.

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 $410 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 per share 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 $410 million in market cap based on 137 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 $820 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	Share Price	Market Cap ($billion)
Intercept Pharmaceuticals, Inc.	ICPT	Phase II	$122.17	$3.02
FibroGen, Inc.	FGEN	Phase I/II	$16.95	$1.06
Raptor Pharmaceuticals	RPTP	Phase II	$9.00	$0.77
Average			**$49.37**	**$1.62**
DURECT Corporation	DRRX	Phase I/II	$1.25	$0.17

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	-	-	-	-	-	-	-	-	-	-	-	-	-	*161.3%*
Remoxy (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5.0	$22.4	$28.9	$40.3
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*348.3%*	*28.6%*	*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	$3.4	$3.1	$12.5	$11.5	$11.5	$11.5	$11.5
YOY Growth	*9.1%*	*-6.4%*	*7.4%*	*-3.6%*	*1.3%*	*5.1%*	*4.6%*	*26.0%*	*6.8%*	*10.4%*	*-7.7%*	*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	$1.5	$9.5	$10.0	$11.0	$12.0
YOY Growth	*-50.5%*	*2.5%*	*17.1%*	*60.1%*	*-5.1%*	*-75.9%*	*-79.1%*	*-82.6%*	*-82.3%*	*-80.3%*	*516.1%*	*5.3%*	*10.0%*	*9.1%*
Total Revenues	**$4.8**	**$4.4**	**$4.7**	**$5.2**	**$19.1**	**$3.6**	**$3.2**	**$3.7**	**$3.5**	**$14.0**	**$26.0**	**$48.9**	**$63.6**	**$95.9**
YOY Growth	*-24.2%*	*-3.1%*	*11.4%*	*21.0%*	*-1.4%*	*-24.4%*	*-28.9%*	*-21.1%*	*-32.3%*	*-26.6%*	*85.6%*	*88.1%*	*30.1%*	*50.8%*
Cost of Goods Sold	$1.0	$1.0	$0.9	$1.0	$3.9	$1.2	$0.9	$2.2	$1.1	$4.4	$4.8	$5.0	$5.2	$5.5
Product Gross Margin	*66.3%*	*61.6%*	*67.1%*	*65.8%*	*65.4%*	*61.1%*	*67.2%*	*35.7%*	*65.0%*	*65.0%*	*58.3%*	*56.5%*	*54.6%*	*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%*	*84.9%*	*91.5%*	*81.3%*	*88.6%*	*86.3%*	*53.8%*	*30.7%*	*25.1%*	*18.8%*
R&D	$5.4	$5.6	$6.7	$6.7	$24.3	$6.6	$7.9	$6.8	$8.0	$29.3	$32.0	$35.0	$40.0	$45.0
% R&D	*112.4%*	*127.0%*	*140.3%*	*128.3%*	*127.2%*	*183.6%*	*248.7%*	*181.8%*	*228.6%*	*209.0%*	*123.1%*	*71.6%*	*62.9%*	*46.9%*
Operating Income	($4.4)	($4.9)	($6.0)	($5.3)	($20.7)	($7.3)	($8.5)	($8.3)	($8.7)	($31.7)	($24.8)	($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)	($2.1)	($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)	($8.8)	($9.2)	($33.8)	($25.8)	($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)	($8.8)	($9.2)	($33.8)	($25.8)	($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)	($0.25)	($0.19)	($0.05)	$0.01	$0.18
YOY Growth	-	-	-	-	-					-	-	-	-	-
Shares Outstanding	113.8	118.8	120.5	120.5	118.5	122.1	132.8	137.9	138.5	132.8	135.0	140.0	145.0	150.0

Source: company filings and Zacks estimates

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