Zacks Small-Cap Research

November 3, 2015
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DURECT Corporation

(DRRX-NASDAQ)

DRRX: *DUR-928 holds great potential for NASH/Kidney Injury, POSIDUR Phase III initiated, and Remoxy NDA filing in 1Q16----Buy*

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	04/30/2015
Current Price (11/02/15)	$2.02
Target Price	**$6.00**

Update

Durect just initiated a new Phase III trial with POSIDUR this fall designed to satisfy the U.S. FDA's request for additional information. Another late stage candidate Remoxy will be filed for NDA in 1Q16 by its partner Pain Therapeutics.

We are especially optimistic about the company's lead epigenomic regulator program DUR-928, which holds great market potential for multiple indications, such as for the management of NAFLD/NASH and acute kidney injury.

We continue to be positive about the Durect story and rate the company shares a Buy rating.

SUMMARY DATA

52-Week High	**$3.23**
52-Week Low	**$0.70**
One-Year Return (%)	**190.35**
Beta	**0.52**
Average Daily Volume (sh)	**241,310**
Shares Outstanding (mil)	**120**
Market Capitalization ($mil)	**$243**
Short Interest Ratio (days)	**7.09**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**14.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	6.3 A	4.6 A	4.3 A	4.3 A	19.4 A
2015	4.8 A	4.4 A	4.7 A	5.1 E	19.1 E
2016					21.0 E
2017					30.7 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.03 A	-$0.05 A	-$0.06 A	-$0.05 A	-$0.20 A
2015	-$0.04 A	-$0.05 A	-$0.05 A	-$0.06 E	-$0.20 E
2016					-$0.23 E
2017					-$0.17 E

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WHAT'S NEW

Durect Exited Third Quarter 2015 with a Strong Balance Sheet

On Nov 2, Durect reported its financial results for the third quarter ended September 30, 2015.

Total revenues for the third quarter of 2015 were $4.7 million, as compared to $4.3 million for the same period last year, an increase of 11.4%. Third quarter revenues for 3Q15 were slightly higher than our estimate of $4.6 million.

Total revenues included revenues from **collaborative research and development** projects and revenues from **product sales**.

Revenue from collaborators was $2.1 million for 3Q15, as compared to $1.8 million for 3Q14, an increase of 17.1%.

Product sales were $2.7 million in third quarter of 2015, compared to $2.5 million for the same period of 2014, an increase of 7.4%. Durect currently generates product revenue from the sale of three product line:

- ALZET ® osmotic pumps for animal research use;
- LACTEL ® biodegradable polymers which are used by our customers as raw materials in their pharmaceutical and medical products; and
- Certain key excipients that are included in REMOXY and one excipient that is included in a currently marketed animal health product.

Since Durect's core business is to develop and commercialize pharmaceutical products, the company does not intend to significantly increase its investments in or efforts to sell or market any of the existing product lines. However, the company is going to continue to make efforts to increase its revenue related to collaborative research and development by entering into additional research and development agreements with third-party collaborators to develop product candidates based on the company's drug delivery technologies.

Cost of goods sold was $0.9 million in 3Q15, compared to $2.3 million in 3Q14.

R&D costs were $6.7 million in 3Q15, compared to $5.4 million in 3Q14.

SG&A expenses were $3.2 million in 3Q15, as compared to $3.1 million for 3Q14.

Net loss for the third quarter of 2015 was $6.5 million ($0.05 per share), as compared to a net loss of $7.1 million ($0.06) for the three months ended September 30, 2014.

At September 30, 2015, Durect had cash and investments of $32.4 million, and a long term debt of $19.7 million. Current cash balance could carry the company's operations into the end of 2016 according to our financial model.

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.

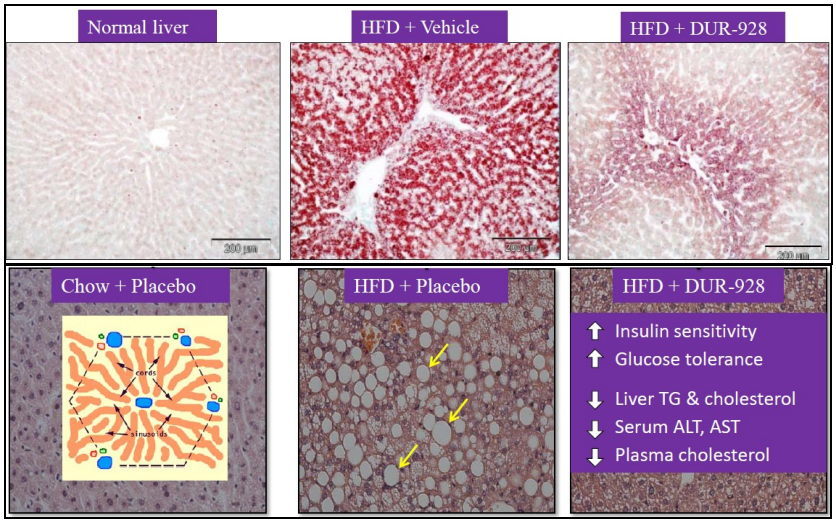
Four of these models represent **acute organ injury**, which include:

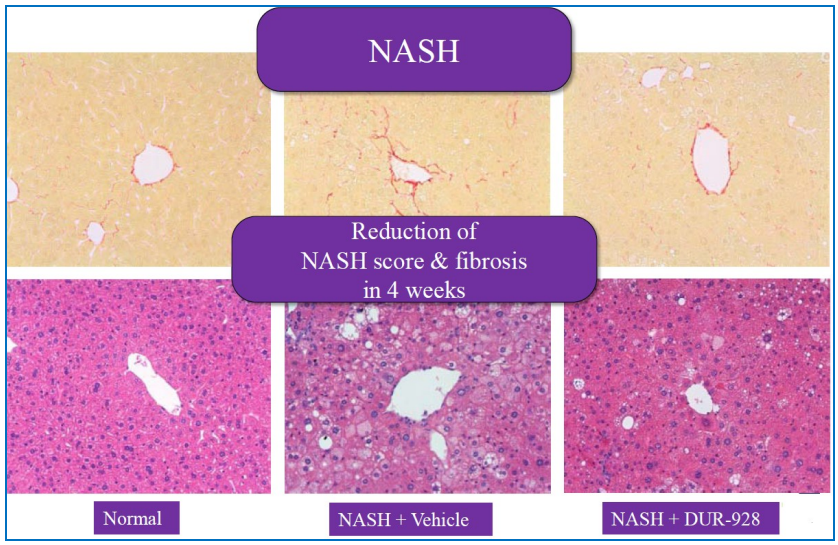
- liver toxicity mouse;
- endotoxin induced septic shock mouse;
- renal ischemia/reperfusion rat; and
- brain ischemia/stroke rat;

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.

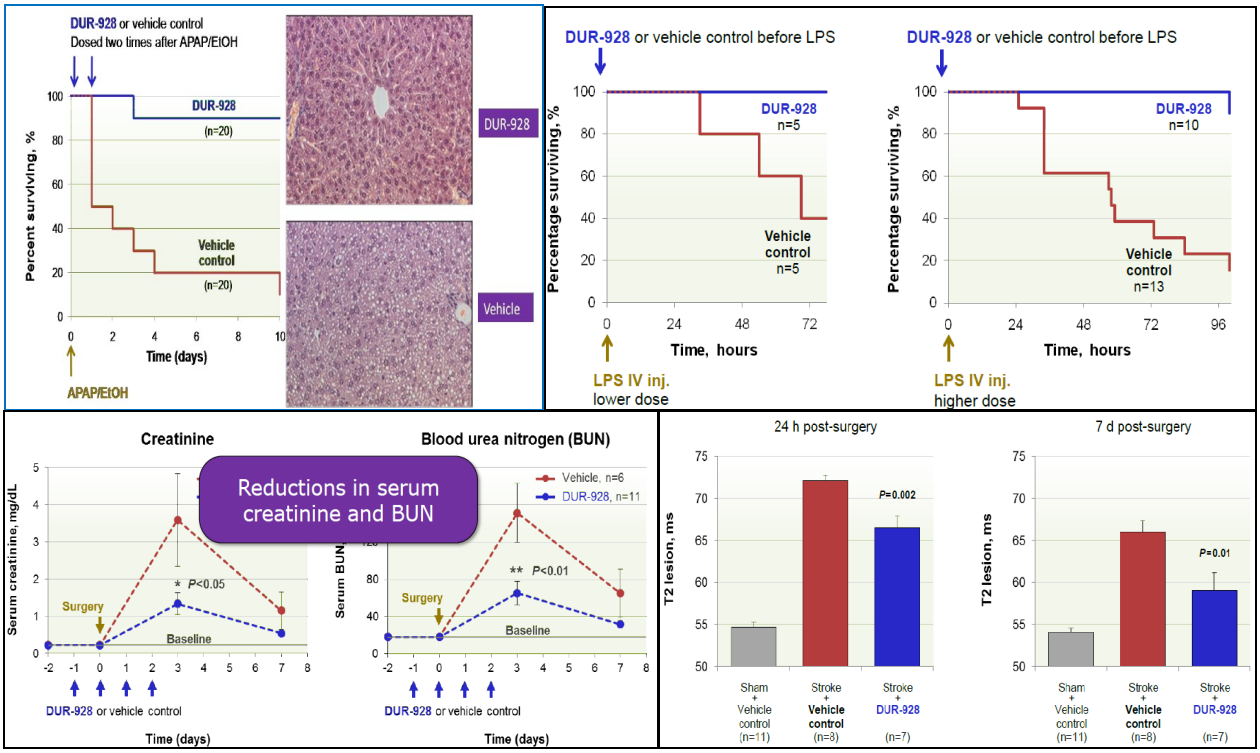




Top three panels represent the high fat diet mouse model. Middle three panels represent high fat diet hamster model. The bottom six panels represent NAFLD/NASH mouse model.

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.

Positive Phase I Data Reported

DURECT recently has completed and reported positive results from two **Phase I** clinical trials with an 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.

DURECT is now moving on to a multiple-dose **Phase I** trial with the **injectable formulation**. Assuming no adverse safety results from this trial, DURECT would then be positioned to commence patient trials in 2016 with an injectable formulation as well as with an oral formulation.

What's next for DUR-928?

Based on the compelling animal data and initial Phase I results, Durect plans to move into **Phase II** trial in 2016 for both oral DUR-928 and injectable DUR-928.

The company is currently evaluating potential indications for DUR-928 in order to prioritize the development program. 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 later this year or early next year.

	2015		2016	Potential Indications
	H1	H2		
DUR-928 Oral Dose (chronic)	Phase I	Phase II Planning	Phase II	NAFLD / NASH, various orphan metabolic conditions
DUR-928 Injectable Dose (acute)	Pre-clinical	Phase I	Phase II	Acute Kidney Injury, various orphan acute injuries
Other NCE's (acute and chronic)	Pre-clinical	Pre-clinical	Phase I	NAFLD / NASH, various orphan indications

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.

New Phase III of POSIDUR Initiated

On June 23, 2015, Durect announced plans to conduct a new Phase III clinical trial **(PERSIST)** with POSIDUR (Saber-bupivacaine) designed to satisfy the U.S. FDA's request for additional information noted in the February 2014 complete response letter. The Phase III trial began to enroll patients in October 2015.

A Brief Background

In February 2014, the U.S. FDA issued a complete response letter (CRL) to Durect Corp, rejecting approval of POSIDUR until some additional data could be analyzed. The FDA indicated in the letter that additional clinical safety trials may be required to demonstrate that POSIDUR was safe when used as described by the proposed label. In September 2014, Durect management met face-to-face with the FDA regarding the next steps for the POSIDUR program. Durect received minutes from the meeting in November 2014 and subsequently submitted a protocol to address the issues and answer the questions posed by the FDA in February 2015. On June 23, 2015, Durect provided an update to investors, essentially noting that the FDA blessed the revised protocol submitted and that the new **Phase III** trial should get underway **this fall**.

As a reminder, Durect has told investors that the CRL on POSIDUR is related to “imbalances” with respect to the safety data. Management has said there were no issues related to efficacy or CMC in the CRL. It seems that the FDA identified inconsistencies in the adverse event profile for POSIDUR among all the clinical studies included in the April 2013 New Drug Application (NDA). Durect conducted these clinical trials and analyzed the efficacy data compared to Saber-placebo. However, some earlier studies, such as the Phase IIb shoulder study conducted in Europe, the company did not actively solicit for adverse events; instead, adverse events were just recorded as reported. In the Phase III BESST trial, adverse events were actively solicited. Non-serious adverse events like discoloration around the injection site and pruritus were higher in the solicited protocols. We believe the FDA would like to get a better sense of the adverse event and safety profile of POSIDUR compared to a true placebo and/or vs. historical data for bupivacaine hydrochloride.

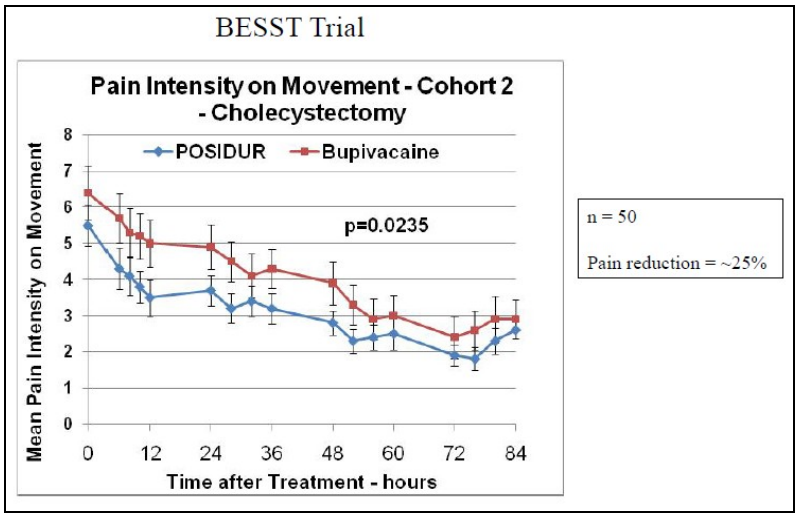
The New Phase III Trial

The new **Phase III** study (NCT02574520) will be conducted in patients undergoing laparoscopic cholecystectomy (gallbladder removal). Target enrollment is 300 patients, randomized one-to-one between POSIDUR and placebo (saline) as a one-time intra-incisional instillation at the close of surgery. The objective of the study will be to evaluate the safety and efficacy of Posidur for the management of postoperative pain. The primary efficacy endpoint will be pain intensity on movement over 0-72 hours after surgery. We believe this is a very manageable study for Durect.

The trial will be conducted at 15-20 centers in the U.S., and we anticipate that enrollment will take roughly twelve months to complete. Management has guided to requiring another six months to analyze and prepare the data, and then re-file the package to the FDA. Once back under review, we expect the FDA to designate a Class-2 review time of six months. External costs for the new Phase III study should be roughly $10 million. We estimate top line data will be available in **4Q16** or **1Q17** and the FDA approval will take place in late 2017 or early 2018.

Previous Data Supports High Likelihood of Success

We believe the hurdle for success of the planned Phase III trial is low given that Durect has already completed a Phase III trial with POSIDUR called BESST (positive top-line data released in January 2012), of which there was a 50-patient cohort specifically in laparoscopic cholecystectomy. Data from the 50 patients following laparoscopic cholecystectomy demonstrated an approximately 25% reduction in pain intensity on movement for the first three days after surgery (p=0.0235) when compared with the active control bupivacaine hydrochloride. Given that the above Phase III trial will compare POSIDUR to placebo, and not an active control, we believe the efficacy endpoint in the above is likely a slam-dunk.



Patients in the study will have access to rescue pain medication, such as opioids. We note in the 50 patient cholecystectomy cohort from BESST noted above, Durect reported a 22% reduction in postsurgical opioid use with POSIDUR compared to bupivacaine hydrochloride. The results just missed statistical significance. However, because in the Phase III trial there is no initial bupivacaine hydrochloride administration, we suspect a large percent of the placebo patients will require opioid rescue medication. Accordingly, we believe Durect will likely meet this key secondary endpoint as well.

In terms of safety, we are expecting the reported adverse event profile from the planned 300 patient laparoscopic cholecystectomy trial will match up similarly to the Phase III BESST study in which management reported POSIDUR as having a similar systemic safety profile to both Saber-placebo and the active bupivacaine hydrochloride comparator. For example, there were no signs of systemic safety issues, only local injection site reactions more common in the POSIDUR and Saber-placebo groups. We believe if the safety and adverse event profile from the planned Phase III trials matches up well with BESST, the FDA will agree the imbalances / inconsistencies seen in previous trials were likely due to data collection methods. This should ultimately answer the key questions from the February 2014 CRL and allow for final approval of the drug.

A Nice Market Opportunity

Management has previously stated that interest in POSIDUR remains high from potential partners, and that finalizing the protocol and getting the Phase III trial underway should allow for discussions to progress in 2015. The company is also moving forward as if they will commercialize POSIDUR themselves. Based on the success of Pacira's EXPAREL®, which posted $188.5 million in revenue in 2014 and Pacira anticipates sales of EXPAREL to rise significantly to $310-$330 million in 2015. EXPAREL only last for 24 hours, while POSIDUR can last 1 to 3 day. This is a big advantage. Therefore, we are confident that POSIDUR has both attractive commercial and partnering potential regardless of the path forward.

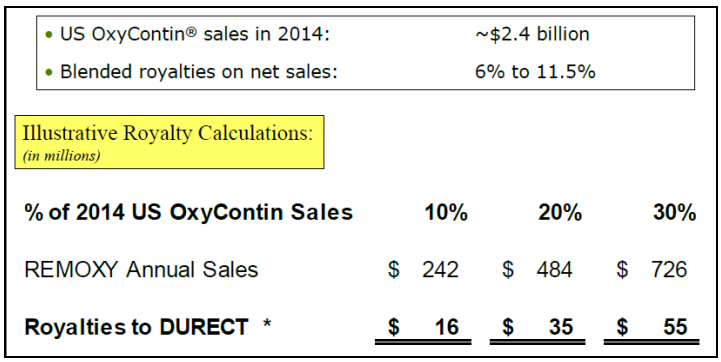
We think it comes down to the terms the company is offered. If attractive enough, we think Durect would like to partner POSIDUR so the company can use that upfront cash to fund DUR-928; however, if the offers to partner are not attractive enough the company is happy to move forward internally. We think POSIDUR offers a potential superior profile, but as second to market the peak sales are likely in the $250 million range.

Update on Remoxy

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.

In May 2015, Pain Therapeutics stated that the transition of the program back from Pfizer was substantially complete. The company recently reported positive top-line data from an abuse potential study in May 2015, and has plans to file the NDA to the U.S. FDA during the first quarter of 2016. After the resubmission is accepted by the FDA, it will take about 6 months for the FDA to review the NDA and make a decision on the approval. This means that Remoxy could be approved in late 2016.

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**

Update on Other Programs

Relday (Risperidone Program)

Relday is a proprietary, long-acting, once-monthly subcutaneous injectable formulation of risperidone for the treatment of schizophrenia.

The company's licensee Zogenix has previously announced positive results from a single-dose **Phase I** clinical trial of Relday. In September 2015, Zogenix announced positive top-line results from a **Phase Ib** multi-dose parallel group clinical trial that enrolled 60 subjects. Zogenix has now initiated efforts to secure a development and commercialization partner for Relday, and plans to begin a **Phase III** program once a

partner is secured.

ORADUR-ADHD Program

In 2013, Durect selected a formulation for the lead program in its ORADUR-ADHD (Attention Deficit Hyperactivity Disorder) 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 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, including the U.S., Europe and Japan, and is engaged in licensing discussions with other companies.

Attractive Valuation

We continue to be optimistic about Durect story and maintain our Buy rating for its shares. We 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 Posidur and Remoxy. The company and its partner Pain Therapeutics plans to submit a NAD for Remoxy in the 1Q16 and we expect the drug to be approved by the end of 2016.

The company has initiated a new Phase III PERSIST trial with its clinical candidate Posidur. We estimate top line data will be available in 4Q16 or 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 2018 with an EPS of $0.11 based on total revenue of $70 million, which include royalty revenue from Posidur and Remoxy, existing product sales and collaborative revenue. EPS will increase to $0.19 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 $360 million in market cap.

But remember this valuation only considers the company's existing products and the two late stage candidates of Remoxy and Posidur. 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. Our $3.00 per share values Durect's DUR-928 program at $360 million in market cap based on 120 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 $720 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, Inc.	ICPT	Phase II	$173.48	$4.22
FibroGen, Inc.	FGEN	Phase I/II	$25.42	$1.54
Raptor Pharmaceuticals Corp.	RPTP	Phase II	$6.06	$0.51
Average			**$68.32**	**$2.09**
DURECT Corporation	DRRX	Phase I	$1.99	$0.24

Source: Zacks Investment Research

INCOME STATEMENT

DURECT Corp	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E	2019 E	2020 E
Posidur (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$26	$12	$32
YOY Growth	-	-	-	-	-	-	-	-	-	-	*161.9%*
Remoxy (Royalty)	$0	$0	$0	$0	$0	$0	$1.0	$9.7	$22.4	$28.9	$40.3
YOY Growth	-	-	-	-	-	-	-	-	*131.4%*	*28.8%*	*39.7%*
Alzet Pumps & Lactel Polymers	$11.1	$3.0	$2.7	$2.7	$3.0	$11.4	$11.5	$11.5	$11.5	$11.5	$11.5
YOY Growth	*-5.0%*	*9.1%*	*-6.4%*	*7.4%*	*-0.4%*	*2.2%*	*1.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Collaborative Revenue	$8.3	$1.7	$1.8	$2.1	$2.1	$7.7	$8.5	$9.5	$10.0	$11.0	$12.0
YOY Growth	*130.0%*	*-50.5%*	*2.5%*	*17.1%*	*67.1%*	*-7.1%*	*10.9%*	*11.8%*	*5.3%*	*10.0%*	*9.1%*
Total Revenues	**$19.4**	**$4.8**	**$4.4**	**$4.7**	**$5.1**	**$19.1**	**$21.0**	**$30.7**	**$69.9**	**$63.6**	**$95.9**
YOY Growth	*26.6%*	*-24.2%*	*-3.1%*	*11.4%*	*19.5%*	*-1.8%*	*10.2%*	*46.1%*	*127.7%*	*-8.9%*	*50.8%*
Cost of Goods Sold	$5.7	$1.0	$1.0	$0.9	$1.1	$4.0	$4.5	$4.8	$5.0	$5.2	$5.5
Product Gross Margin	*49.0%*	*66.9%*	*61.6%*	*67.1%*	*63.0%*	*64.7%*	*60.9%*	*58.3%*	*56.5%*	*54.8%*	*52.2%*
SG&A	$12.3	$2.8	$2.7	$3.2	$3.2	$11.9	$13.0	$14.0	$15.0	$16.0	$18.0
% SG&A	*63.3%*	*59.1%*	*61.3%*	*67.0%*	*62.7%*	*62.6%*	*61.9%*	*45.6%*	*21.5%*	*25.1%*	*18.8%*
R&D	$22.4	$5.4	$5.6	$6.7	$7.5	$25.2	$30.0	$32.0	$35.0	$40.0	$45.0
% R&D	*115.6%*	*112.4%*	*127.0%*	*140.3%*	*147.1%*	*132.0%*	*142.9%*	*104.3%*	*50.1%*	*62.9%*	*46.9%*
Operating Income	($21.0)	($4.4)	($4.9)	($6.0)	($6.7)	($22.0)	($26.5)	($20.1)	$14.9	$2.4	$27.4
Operating Margin	*-108.2%*	-	-	-	-	*-115.7%*	*-126.2%*	*-65.5%*	*21.3%*	*3.8%*	*28.6%*
Interest & Other Net	($1.0)	($0.4)	($0.5)	($0.5)	($0.5)	($2.0)	($2.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	($22.0)	($4.9)	($5.5)	($6.5)	($7.2)	($24.0)	($28.5)	($21.1)	$13.9	$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
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($22.0)	($4.9)	($5.5)	($6.5)	($7.2)	($24.0)	($28.5)	($21.1)	$13.9	$1.4	$26.4
YOY Growth	-	-	-	-	-	-	-	-	-	*-89.7%*	*1756.3%*
Reported EPS	($0.20)	($0.04)	($0.05)	($0.05)	($0.06)	($0.20)	($0.23)	($0.17)	$0.11	$0.01	$0.19
YOY Growth	-	-	-	-	-	-	-	-	-	-	-
Shares Outstanding	111.6	113.8	118.8	120.5	122.0	118.8	122.0	125.0	130.0	135.0	140.0

Source: company filings and Zacks estimates

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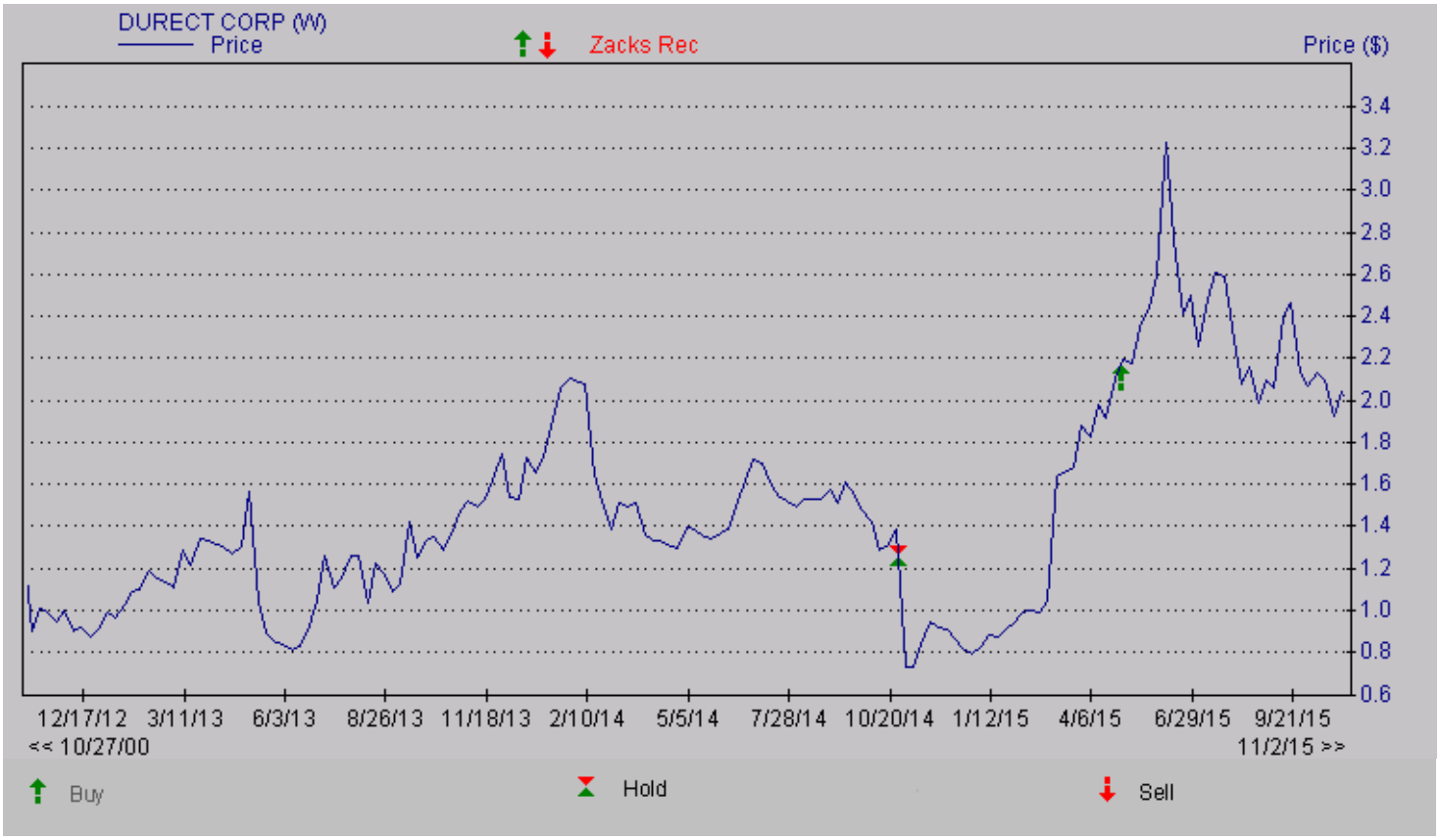

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