Zacks Small-Cap Research

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Durect Corp (DRRX-NASDAQ)

DRRX: Zacks Company Report

DRRX: *DUR-928 on track to enter Phase II studies, and holds great potential for long term growth. We are still optimistic about DRRX even with the failure of POSIMIR program.*

OUTLOOK

Durect is a late stage biotech company with Remoxy approval expected in 2019.

We are especially optimistic about the company's epigenetic 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 2017/2018.

We continue to be positive about the Durect story.

Current Price (11/01/17)	$0.79
Valuation	**$6.00**

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.78**
One-Year Return (%)	**-33.05**
Beta	**1.63**
Average Daily Volume (sh)	**1,196,851**
Shares Outstanding (mil)	**147**
Market Capitalization ($mil)	**$116**
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 (%)	**-17.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**-4.8**
P/E using 2018 Estimate	**-6.0**
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 A	14.0 A
2017	4.6 A	4.3 A	20.8 A	7.4 E	37.0 E
2018					37.0 E

Price/Sales Ratio (Industry = 2.5x)

	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	-$0.06 A	-$0.26 A
2017	-$0.06 A	-$0.07 A	$0.04 A	-$0.05 E	-$0.13 E
2018					-$0.14 E

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

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WHAT'S NEW

Update on Third Quarter Financials

The company recorded a **total revenue** of $20.7 million in the third quarter ended September 30,2017, compared to $3.7 million in the third quarter of last year.

Revenue from R&D collaborations was $5.6 million in third quarter 2017, compared to $0.4 million in third quarter 2016. A large portion of that increase related to the recognition of deferred revenue from upfront fees already received by the company. Per the conference call, management indicated that even if taking out the deferred revenue, collaborative revenue increased by about $0.7 million during the current quarter compared to the third quarter last year.

Product revenue, largely from the sale of ALZET pumps and LACTEL polymers, was $2.6 million in the third quarter 2017, as compared to $3.4 million in the third quarter 2016. Almost half of that difference related to some excipient sales in the third quarter 2016 and there were no similar sales in the third quarter 2017. The business of ALZET and LACTEL continue to be strongly cash flow positive for the company.

The company had a **new line item** in revenue this quarter, which recorded $12.5 million upfront fee received from Indivior in connection with the patent agreement signed during the third quarter of 2017. We will discuss this deal later.

Cost of product sales was $3.1 million in the third quarter 2017, this was impacted by a charge of around $2 million related to the company's excipients. The company took this charge given the negative POSIMIR Phase III results. But the company did not get rid of any of these materials. If the company is able to sell these excipients later, then at that time, the company would have revenue, but no associated cost of goods sold.

R&D expense was $8.4 million in the third quarter 2017, compared to $6.8 million in the third quarter 2016, driven primarily by a large increase in POSIMIR Phase III trial expenses.

SG&A expenses were $3.1 million in the third quarter 2017, compared to $3 million in the third quarter 2016.

The company reported net income of $6.1 million in the third quarter 2017, as compared to a net loss of $8.8 million in the third quarter of 2016.

At September 30, Durect had cash and investments of $41.8 million, which compared to a $33.6 million at June 30, 2017, and $25.2 million at December 31, 2016.

A $17.5 Million Patent Purchase Agreement with Indivior PLC

The Patent Deal

On October 2, 2017, Durect announced a patent purchase agreement with Indivior UK Limited, an affiliate of Indivior PLC (INDV.L).

Pursuant to the agreement, Durect assigned certain of its U.S. patent rights to Indivior. This assignment may provide further intellectual property protection for RBP-7000, Indivior's investigational once-monthly injectable risperidone product for the treatment of schizophrenia. Indivior has submitted a New Drug Application (NDA) for RBP-7000 to the U.S. Food and Drug Administration (FDA). We expect the approval of RBP-7000 by the FDA in 2H18.

Per the agreement, Indivior has made an upfront non-refundable payment to Durect of $12.5 million, with the potential for an additional $5 million based on a regulatory milestone, as well as quarterly earn-out payments that are based on a single digit percentage of U.S. net sales for certain products covered by the patent rights, including RBP-7000. The patent rights include granted patents extending through at least 2026. Indivior estimates peak US sales of RBP-7000 in the range of 200 and 300 million dollars.

The Implication of the Deal

We think this is a great deal for Durect.

The deal not only boosts Durect's balance sheet, but also validate the company's long-acting risperidone formulation technology.

Durect's long-acting injectables are designed to achieve stable delivery of small-molecule and biologic therapeutics for periods of days to months following a single subcutaneous, intramuscular, or other localized injection. The company's biocompatible, bioerodible technologies employ varied and customizable sets of components, allowing the formulation to be fine-tuned to suit the active pharmaceutical ingredient (API), the physiological environment, and the desired performance characteristics of the commercial product.

Durect's long-acting injectable technologies demonstrate the following advantages:

- High drug loading—Drug loading as high as 30%, permitting smaller injection volumes
- Controlled onset and release—Rapid onset and stable release of drug over time, with little to no post-injection "burst"
- Stabilization—Proteins, peptides, and small molecules can be shielded from water and biologically active enzymes to prolong in vivo activity
- Ease of administration—Low viscosity and small volumes for easier, less painful injections
- Ease of manufacture—scalable, low-cost manufacturing
- Strong patent protection—covered by U.S. and foreign patents

Update on POSIMIR®

On Oct. 19, 2017, DURECT reported that PERSIST, the **Phase III** clinical trial for POSIMIR® (SABER®-Bupivacaine), did not meet its primary efficacy endpoint of reduction in pain on movement over the first 48 hours after surgery as compared to standard bupivacaine HCl. While results trended in favor of POSIMIR versus the comparator, they did not achieve statistical significance.

The Posimir (SABER®-Bupivacaine) Program

The company **completed** the enrollment of patients in PERSIST, a POSIMIR **Phase III** clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery in June 2017.

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.

In May, 2017, Durect announced a development and commercialization agreement with Sandoz AG, a division of Novartis (NVS), to develop and market in the United States Durect's POSIMIR® (SABER®-

Bupivacaine). Under the terms of the agreement, Sandoz will make an upfront payment to DURECT of $20 million, with the potential for up to an additional $43 million in development and regulatory milestones, up to an additional $230 million in sales based milestones, as well as a tiered double digit royalty on product sales in the **United States**.

The company and Sandoz, the company's licensee for commercialization rights for POSIMIR in the United States, will be working to understand the trial results more fully in the coming weeks.

With the failure of the Phase III trial, we believe Durect will terminate the development of POSIMIR and shift its focus to the company's epigenetic program DUR-928.

Focus will Be Shifted to DUR-928 Development Program

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 Epigenetic 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-928 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).

Update on 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 was a dose ranging (50 mg and 200 mg), single-ascending-dose safety and pharmacokinetic (PK) study of **oral DUR-928** in subjects with NASH and matched control subjects (MCS). This study was conducted in successive cohorts evaluating single-dose levels (first a low dose and then a high dose) of oral DUR-928. Both cohorts consisted of 10 NASH patients and 6 MCS.

Table 1. Patient Demographics (mean ±SD)

	Cohort 1 (50 mg)		Cohort 2 (200 mg)	
Demographics	NASH	MCS	NASH	MCS
# of Patients	10	6	10	6
Age (yrs)	53.4 (10.7)	56.8 (6.5)	53.2 (12.9)	54.7 (6.0)
BMI (kg/m2)	34.7 (6.2)	31.2 (2.4)	36.6 (6.4)	33.2 (4.4)
Gender (M/F)	5/5	5/1	5/5	3/3
Baseline ALT (U/L)	66.7 (18.9)	19.3 (6.5)	78.9 (45.5)	20.8 (4.8)
Cirrhotic Patients	2	--	3	--
Non-Cirrhotic Patients	6	--	5	--
Undetermined	2	--	2	--

On April 24, 2017, Durect presented the updated **Phase Ib** data at the International Liver Congress™2017 (the 52nd annual meeting of the European Association for the Study of the Liver (EASL)) in Amsterdam.

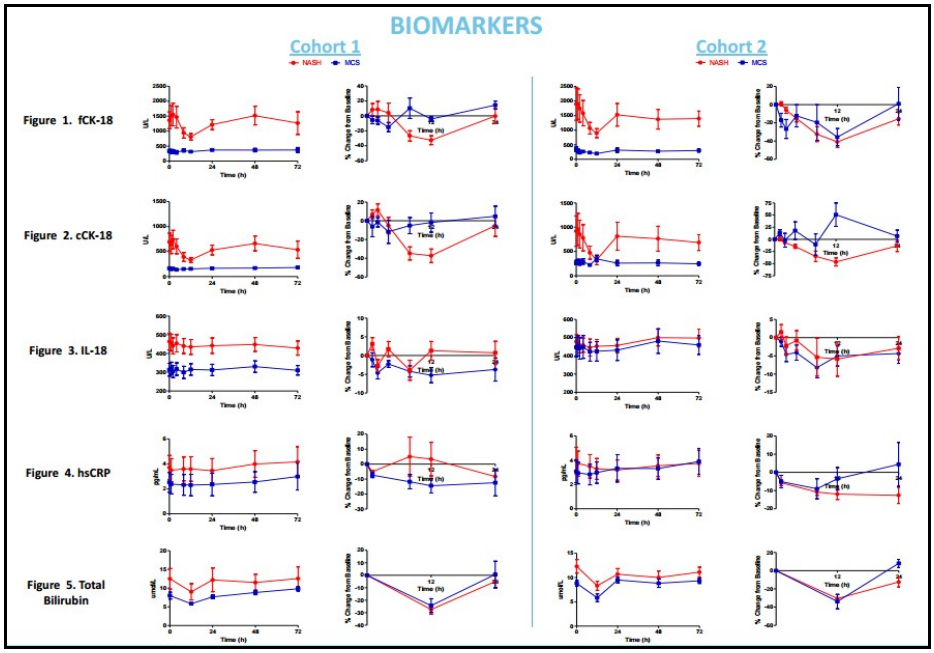
In both cohorts, DUR-928 was **well tolerated overall**. There was approximately a 10-30% increase in DUR-928 exposure in NASH patients compared to MCS. A single serious adverse event (shortness of breath), designated as possibly related to study drug, was reported in Cohort 2 in a NASH patient with a prior history of arrhythmia and an ongoing viral infection; no unusual abnormal biochemistry was observed and the symptom spontaneously resolved.

Table 2. Pharmacokinetic Parameters (mean ±SEM)

	Cohort 1		Cohort 2	
PK Parameters	NASH	MCS	NASH	MCS
Cmax (ng/mL)	113.2 (36.3)	94.0 (27.4)	332.7 (99.5)	260.5 (54.8)
Tmax (hr)	2.4 (0.8)	3.0 (1.1)	2.9 (1.2)	2.7 (1.0)
T½ (hr)	1.6 (0.2)	1.7 (0.3)	1.9 (0.4)	1.7 (0.4)
AUClast (ng*hr/mL)	512.7 (219.1)	476.5 (187.6)	1723.7 (470.9)	1316.9 (203.4)
AUCinf (ng*hr/mL)	528.1 (216.4)	487.9 (190.2)	1732.6 (470.5)	1325.5 (202.9)

Exploratory biomarker analysis indicated that a single oral dose of DUR-928 resulted in reductions from baseline in the levels of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, hsCRP and IL-18 in NASH patients.

- The decrease of full-length CK-18 (a generalized cell death marker) at 12 hours was approximately 33% in the NASH patients in the low dose cohort and approximately 41% in the high dose cohort. The decrease of cleaved CK-18 (a cell apoptosis marker) at 12 hours was approximately 37% in the NASH patients in the low dose cohort and approximately 47% in the high dose cohort.
- The decrease in total bilirubin (a liver function marker for which a decrease would be seen as positive) at 12 hours in the NASH patients was approximately 27% in the low dose cohort and approximately 31% in the high dose cohort.
- High sensitivity C-Reactive Protein (hsCRP), a marker of inflammation, trended higher at 12 hours in the NASH patients by approximately 3% in the low dose cohort but trended lower by approximately 12% in the high dose cohort.
- IL-18, an inflammatory mediator implicated in both liver and kidney diseases, trended lower at 12 hours by approximately 5% in both the low dose cohort and in the high dose cohort.



Animal Data Further Indicate DUR-928's Potential for NASH

In March 2017, at the AASLD Emerging Trends in Non-Alcoholic Fatty Liver Disease Meeting, Durect presented a poster in a STAM mouse model with DUR-928.

The animal study was designed as a two-phase study.

- **Phase I**: Weeks 5–9, daily oral doses of 10 or 50 mg/kg DUR-928 or Vehicle (n=8-9/treatment group)
- **Phase II**: Weeks 9–13, daily oral doses of 50 mg/kg DUR-928 or Vehicle (n=6-8/treatment group)
- Studies were terminated upon completion of dosing
- Baseline measurements were collected from untreated STAM™ mice at Week 9

Data from the animal study were pretty impressive.

Phase I – Weeks 5-9

- Four weeks of daily oral DUR-928 treatment during the early stages of NAFLD/NASH exhibited dose-dependent effects:
  - Significant decrease in NAS
  - Trend of decrease of liver fibrosis was observed
  - Significant reduced hepatic expression of *Tnfα* and trend of decrease of *Mcp-1*

Phase II – Weeks 9-13

- Four weeks of daily oral DUR-928 treatment when liver fibrosis was established resulted in:
  - Significant decrease in liver fibrosis
  - Significant decrease in hepatocyte ballooning
  - Trend of reduced hepatic expression of fibrotic genes, Collagen 1a1 and 3a1
- Hepatic nodule formation, which progresses to hepatocellular carcinoma in this model, was also reduced in total number, size and incidence in DUR-928-treated mice

Also, in a recently published paper in the journal Metabolism (71(2017) 83-93), DUR-928 has demonstrated great potential to treat liver injury in an animal model:

- The mortality effect for DUR-928 in the animal model was striking,
- Only 10% of the animals survived at 96 hours without DUR-928 vs 90% survival with DUR-928,
- These results suggest the utility of DUR-928 for multi-organ injury,
- These results show the potent anti-inflammatory effect of DUR-928 (shown as significant reduction of cytokines and inflammatory cell infiltration in the tissues),

The data from the Phase Ib trial and the animal studies are 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.

Update on 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 (first a low dose and then a high dose) evaluating single-dose levels of DUR-928 administered **by injection.**

The company recently **completed the Phase Ib** study. The low dose cohort enrolled 6 kidney function impaired patients and 3 matched control subjects, and the high dose cohort enrolled 5 kidney function impaired patients and 3 matched control subjects.

In this trial, DUR-928 was well tolerated among all subjects and the PK parameters between the kidney function impaired patients and the matched control subjects were comparable.

In addition, Durect has held a pre-IND meeting with the Cardiovascular and Renal Products Division of the FDA, and the company is utilizing feedback from that meeting as well as from its clinical advisors to prepare an IND which is required to enable a future kidney disease clinical trial **in the United States**.

Topical Formulation

Durect **completed** an initial **exploratory Phase Ib** trial in **psoriasis** patients (n = 9 evaluable patients) in Australia. The decision to proceed with clinical testing in psoriasis was based on the anti-inflammatory and cell survival properties of DUR-928, including the downregulation of IL-17, full length CK-18, cleaved CK-18, as well as the results of a psoriasis study with DUR-928 in mice.

The **Phase Ib** trial was conducted with intradermal micro injections of DUR-928, and the company thinks the results warrant further investigation. As a result, the company has developed several topical formulations of DUR-928 that the company is evaluating for a topical application microplaque trial which will commence next year.

There is a large unmet medical need for new topical drugs for psoriasis for use prior to systemic biologic treatments which often have significant associated side effects.

Future Development Plans

Durect is working with its clinical advisors to design several **Phase II** studies and is planning to submit INDs which are required to enable these studies to take place in the United States in 2017.

Oral Administration:
The company is actively working towards initiating a **Phase II** trial in primary sclerosing cholangitis **(PSC)** with orally administered DUR-928. The protocol has been reviewed by the FDA and IND is now open. Clinical trial site preparation is underway, and the company is targeting dosing the first patient **by the end of 2017**. Durect has received orphan drug designation for DUR-928 to treat patients with PSC. PSC is a chronic liver disease characterized by a progressive cause of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. It is an orphan medical condition for which there is no established medical treatment.

Injectable Administration:
Durect now has an open IND for an initial **Phase II** trial of injectable DUR-928. The company is currently finalizing the protocol based on detailed input received in October 2017 from AASLD. This Phase II study will be conducted in patients with moderate and severe acute liver function impairment to assess the safety and pharmacokinetics of several doses of DUR-928.

At AASLD poster presentation, DUR-928 demonstrated dose-dependent effect in stabilizing mitochondrial membranes, which is an important factor in cell viability and prevention of cell death. In this poster, DUR-928 demonstrated 90% survival vs. 10% survival on placebo, when the toxicity was caused by injected acetaminophen. This poster also demonstrated the pharmacological effect of DUR-928 in animal models of both endotoxin and drug induced multiple organ injuries, including the liver, the kidney and the lungs.

Topical Administration:
The company has had pre-IND interactions with the FDA and is incorporating FDA's comments in its upcoming IND while the company is actively working with expert advisors to finalize the study protocol for a **Phase II** proof-of-concept study. The company expects to initiate this study in the **first half of 2018**.

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).

Per 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.

Update on Remoxy

In March 2017, Pain Therapeutics announced that it plans to resubmit the REMOXY ER NDA after completing two additional studies regarding REMOXY ER based on guidance obtained in a meeting with the FDA. The two studies are a clinical abuse potential study via the intranasal route of abuse and a non-clinical abuse potential study using household solvents. Pain Therapeutics stated that it expects to complete these studies by year end 2017.

In March 2017, the company's partner Pain Therapeutics announced that it plans to resubmit the REMOXY ER NDA after completing two additional studies regarding REMOXY ER based on guidance obtained in a recent meeting with the FDA. The two studies are a clinical abuse potential study via the intranasal route of abuse and a non-clinical abuse potential study using household solvents. Pain Therapeutics stated that it expects to complete these studies by year end 2017.

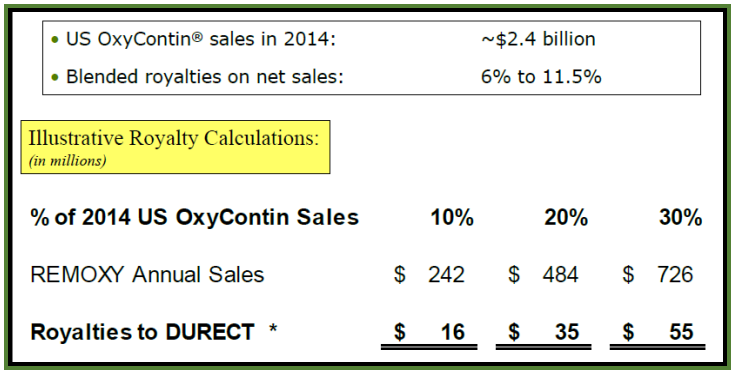
In October 2017, Pain Therapeutics announced that there is a pre-NDA guidance meeting with the FDA planned for November 14, 2017 and Pain Therapeutics is planning an NDA resubmission in the first quarter of 2018.

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**

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 reported that a **Phase III** study conducted in Taiwan has achieved positive results.

Durect retains rights to all other markets in the world, notably including the U.S., Europe and Japan. The company intends to reach out with these Phase III data to potential development and commercialization partners for major markets not licensed to Orient Pharma.

Attractive Valuation

We continue to be optimistic about Durect story even with the failure of POSIMIR® program. We adjusted our price target to $6.00 from previous $7:00 per share due to the failure of POSIMIR program.

Durect is a late development stage biotech company with a Phase III candidate Remoxy. Although Remoxy received a CRL from the FDA, we still believe this is a viable program and will be approved in 2019.

Based on our financial model, we expect the company will break even in 2020 with based on total revenue of $77 million, which include royalty revenue from Remoxy, existing product sales and collaborative revenue.

As we discussed above, among the company's multiple candidates, we are especially optimistic about the company's epigenetic regulator program **DUR-928**, which holds great potential for multiple indications, such as NASH and acute kidney injury.

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 $6.00 per share values the company at $882 million in market cap based on 142 million outstanding shares, which is still conservative compared to its peers in our view.

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 ($million)*
Intercept Pharmaceutical	ICPT	Phase II	$115.00	$2,860.00
FibroGen	FGEN	Phase I/II	$41.50	$2,959.00
Raptor Pharmaceuticals	RPTP	Phase II	$9.00	$770.00
Average			**$55.17**	**$2,196.33**
DURECT Corporation	DRRX	Phase I/II	$0.82	$121.00

Source: Zacks Investment Research

PROJECTED INCOME STATEMENT

DURECT Corp	Q1	Q2	Q3	Q4	2016 A	Q1	Q2	Q3	Q4	2017 E	2018 E	2019 E	2020 E
Posimir (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*
Remoxy (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0	$5.0	$15.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*200.0%*
DUR-928	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Alzet Pumps & Lactel Polymers	$3.2	$2.8	$3.4	$2.8	$12.1	$4.1	$3.1	$2.6	$3.4	$13.2	$12.0	$12.0	$12.0
YOY Growth	5.1%	4.6%	26.0%	-4.3%	7.6%	29.6%	9.5%	-22.0%	22.3%	8.9%	-9.3%	0.0%	0.0%
Collaborative Revenue	$0.4	$0.4	$0.4	$0.7	$1.9	$0.4	$1.3	$5.6	$4.0	$11.3	$25.0	$25.0	$50.0
YOY Growth	-75.9%	-79.1%	-82.8%	-67.4%	-76.0%	3.6%	241.8%	1491.5%	442.0%	501.3%	121.2%	0.0%	100.0%
Revenue from sale of IP rights								$12.5		$12.5			
Total Revenues	**$3.6**	**$3.2**	**$3.7**	**$3.5**	**$14.0**	**$4.6**	**$4.3**	**$20.75**	**$7.4**	**$37.03**	**$37.0**	**$42.0**	**$77.0**
YOY Growth	-24.4%	-28.9%	-21.1%	-31.9%	-26.7%	26.6%	36.8%	454.3%	110.4%	164.0%	-0.1%	13.5%	83.3%
Cost of Goods Sold	$1.2	$0.9	$2.2	$1.0	$5.3	$1.5	$0.9	$3.1	$1.3	$6.9	$5.0	$5.2	$5.5
Product Gross Margin	*61.1%*	*67.2%*	*35.7%*	*65.6%*	*56.4%*	*62.7%*	*69.7%*	*-17.4%*	*61.8%*	*48.0%*	*58.3%*	*56.7%*	*54.2%*
SG&A	$3.1	$2.9	$3.0	$2.8	$11.8	$3.0	$3.7	$3.1	$3.5	$13.4	$17.5	$22.5	$25.0
% SG&A	*84.9%*	*91.5%*	*81.3%*	*80.5%*	*84.3%*	*66.6%*	*85.2%*	*15.1%*	*47.3%*	*36.1%*	*47.3%*	*53.6%*	*32.5%*
R&D	$6.6	$7.9	$6.8	$8.0	$29.3	$7.5	$9.1	$8.4	$9.0	$34.0	$35.0	$40.0	$45.0
% R&D	*183.6%*	*248.7%*	*181.8%*	*227.2%*	*208.7%*	*165.3%*	*210.2%*	*40.4%*	*121.6%*	*91.8%*	*94.6%*	*95.2%*	*58.4%*
Operating Income	($7.3)	($8.5)	($8.3)	($8.3)	($32.4)	($7.6)	($9.4)	$6.1	($6.4)	($17.2)	($20.5)	($25.7)	$1.5
Operating Margin	-	-	-	-	-	-	-	-	-	-	*-55.4%*	*-61.2%*	*1.9%*
Interest & Other Net	($0.5)	($0.5)	($0.5)	($0.5)	($2.1)	($0.5)	($0.6)	($0.0)	($0.5)	($1.6)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	($7.9)	($9.0)	($8.8)	($8.8)	($34.5)	($8.1)	($9.9)	$6.1	($6.9)	($18.8)	($21.5)	($26.7)	$0.5
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
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%*
Net Income	($7.9)	($9.0)	($8.8)	($8.8)	($34.5)	($8.1)	($9.9)	$6.1	($6.9)	($18.8)	($21.5)	($26.7)	$0.5
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*24.2%*	*-101.9%*
Reported EPS	($0.06)	($0.07)	($0.06)	($0.06)	($0.26)	($0.06)	($0.07)	$0.04	($0.05)	($0.13)	($0.14)	($0.18)	$0.00
YOY Growth					-					-	-	-	-
Shares Outstanding	122.1	132.8	137.9	139.6	133.1	141.8	142.5	147.2	149.0	145.1	150.0	152.0	155.0

Source: company filings and Zacks estimates

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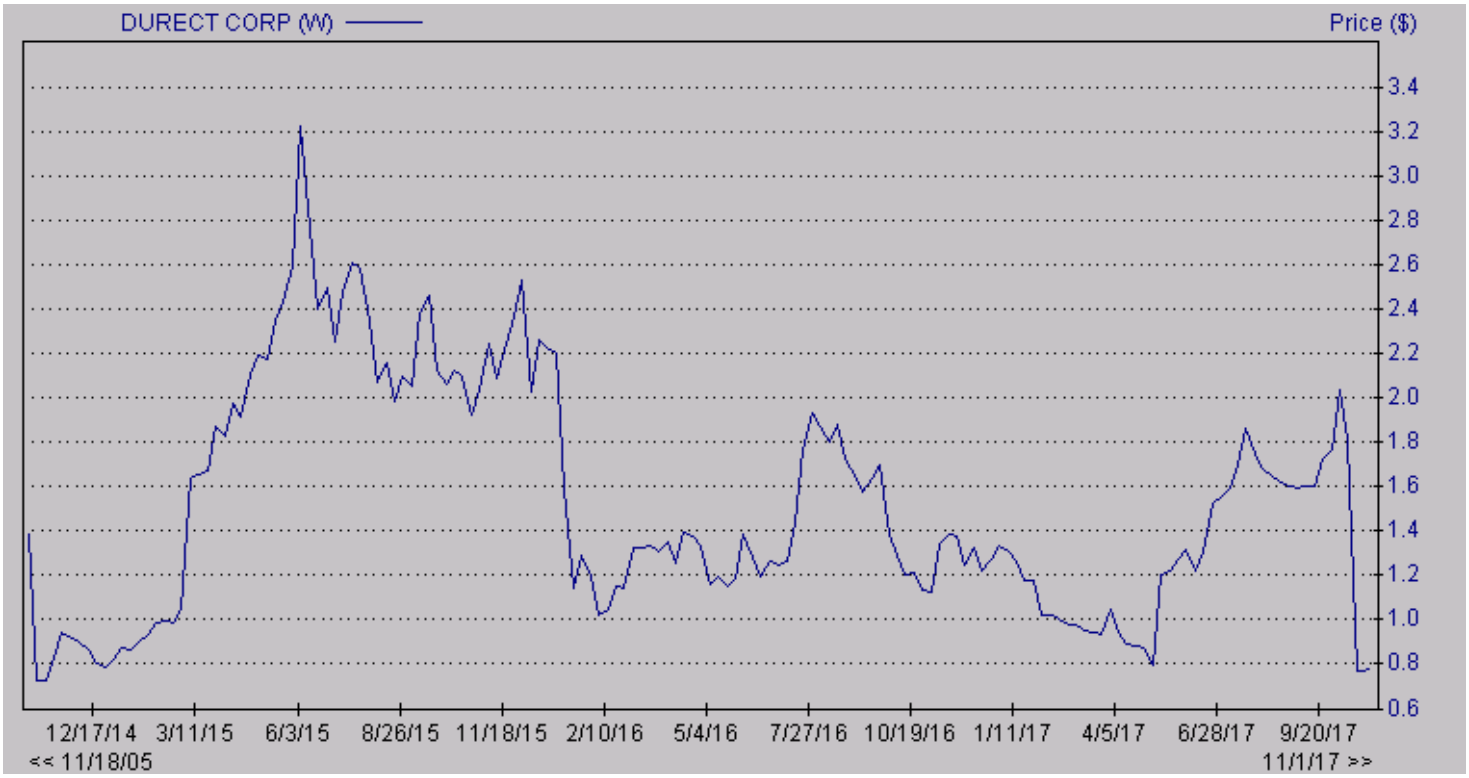

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