Zacks Small-Cap Research

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Durect Corp (DRRX-NASDAQ)

DRRX: Zacks Company Report

DRRX: *Deal with Sandoz for Posimir not only boosts B/S, but also validates technology and program; DUR-928 on track to enter Phase II studies, and holds great potential for long term growth*

OUTLOOK

Durect is a late stage biotech company with Posimir approval expected to be in 2018 and 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.

We continue to be positive about the Durect story.

Current Price (05/17/17)	$1.16
Valuation	**$7.00**

SUMMARY DATA

52-Week High	**$1.94**
52-Week Low	**$0.78**
One-Year Return (%)	**0.87**
Beta	**1.51**
Average Daily Volume (sh)	**1,922,592**
Shares Outstanding (mil)	**142**
Market Capitalization ($mil)	**$165**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**50**
Insider Ownership (%)	**10**
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	8.5 E	12.2 E	11.4 E	36.7 E
2018					42.0 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	-$0.03 E	-$0.01 E	-$0.02 E	-$0.12 E
2018					-$0.11 E

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

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WHAT'S NEW

Update on 1Q17 Financials

On May 10, 2017, DURECT Corporation (DRRX) announced financial results for the three months ended March 31, 2017.

Total revenues were $4.6 million for the three months ended March 31, 2017 as compared to total revenues of $3.6 million for the three months ended March 31,2016, an increase of 27%.

Product sales for 1Q17 were $4.1 million, compared to $3.2 million for the same period of 2016, an increase of 30%.

Collaborative R&D revenue was $0.4 million for 1Q17, compared to $0.4 million for 1Q16.

COGS for 1Q17 was $1.5 million, compared to $1.2 million for 1Q16.

R&D expenses for 1Q17 were $7.5 million, compared to $6.6 million for 1Q16.

SG&A expenses for 1Q17 were $3.0 million, compared to $3.1 million for 1Q16.

Net loss for the first quarter of 2017 was $8.1 million, as compared a net loss of $7.9 million for the first quarter of 2016.

At March 31, 2017, cash and investments were $16.7 million. Debt at March 31, 2017 was $19.9 million.

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).

A $293 Million Deal with Sandoz for POSIMIR® in the United States

The Development and Commercialization Deal

On May 8, 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), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery.

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 $43 million could be received when Durect resubmits the NDA and get approval for Posimir which could be done in 1Q18.

DURECT will remain responsible for the completion of the ongoing PERSIST **Phase III** clinical trial for POSIMIR as well as FDA interactions through approval. The deal is expected to close in the second quarter of 2017.

The Posimir (SABER®-Bupivacaine) Program

The company expects to finish dosing patients in PERSIST, a POSIMIR **Phase III** clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery, in the second

quarter of 2017 and to have top-line results in the fourth quarter this year which would then tee up a resubmission for NDA.

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 outside the US.

Our Takeaway

We think this is a great deal for Durect. Sandoz has a very strong sales/marketing team and has a great presence in the US. Sandoz has a differentiated product portfolio including a range of state-of-the-art technologies, formulations and devices. In the U.S., Sandoz Inc. has a dedicated hospital sales and marketing organization, with expertise and relationships, which will be employed to deliver POSIMIR to the market.

The deal not only boosts Durect's balance sheet, but also validate the company's technology and clinical program.

The market for a non-opioid post-surgical pain product is quite large. One piece of evidence for this is Pacira and their product Exparel. Pacira has a $1.9 billion market cap on the basis of Exparel, which is projected to have about $300 million in revenue in 2017. If approved, POSIMIR will compete quite effectively in this marketplace:

- There is an unmet medical need for a product with POSIMIR's extended duration of action and potential to reduce the need for opioids (with their associated side-effects, risks of leading to addiction, and costs).
- POSIMIR would have an extended duration of action (up to 3 days).
- Durect's development program will have generated data from multiple common surgeries including hernia, shoulder and gall bladder removal.
- POSIMIR is administered simply and rapidly into the surgical site under visual supervision, which puts the drug closer to the affected nerves.
- This administration technique also facilitates use in laparoscopic procedures with multiple ports, which is relevant given the number of laparoscopic surgeries today and the overall trend toward less invasive procedures.

Update on 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.

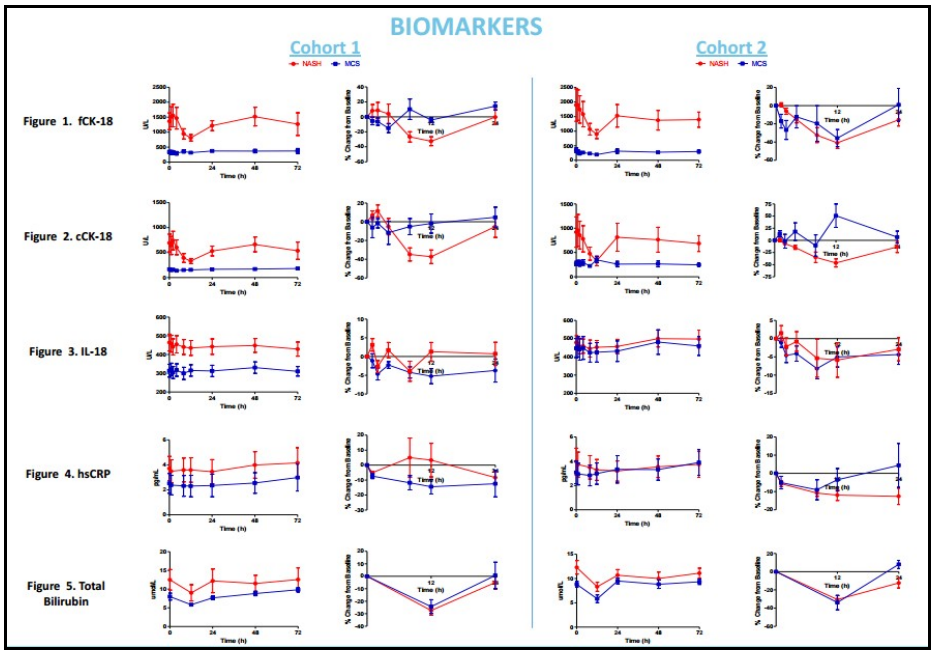
In both cohorts, DUR-928 was **well tolerated overall**. There was approximately a 10-30% increase in DUR-928 exposure in NASH patients compared to MCS. A single serious adverse event (shortness of breath), designated as possibly related to study drug, was reported in Cohort 2 in a NASH patient with 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.



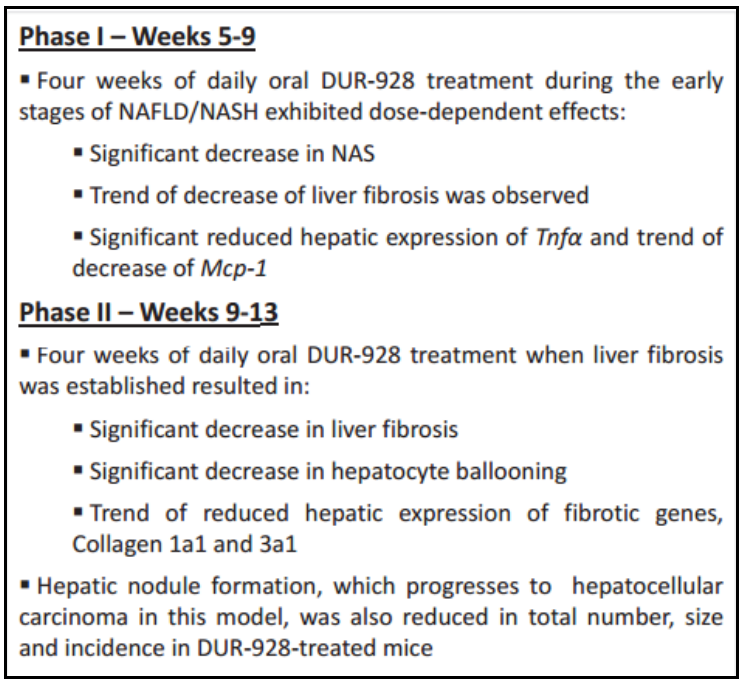
Animal Data Further Indicate DUR-928's Potential for NASH

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.



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 low dose cohort consisted of 6 kidney function impaired patients and 3 matched control subjects. After a PK/safety review of this cohort, the study has proceeded to the high dose cohort utilizing a dose four times larger than the low dose cohort. Data from the **low dose** cohort showed the PK parameters between the kidney function impaired patients and the matched control subjects were comparable.

The **high dose** cohort of this study is currently enrolling patients.

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 conducted 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 this 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.

Durect plans to conduct **at least one Phase II** trial in 2017. The company is actively working towards a **Phase II** trial in Primary Sclerosing Cholangitis **(PSC)**, with an oral formulation of DUR-928. 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.

The company also plans to select lead **topical formulations** for DUR-928 that will be taken into a proof-of-concept clinical trial in psoriasis patients in 2017.

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 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.

On March 20, 2017, Pain Therapeutics announced positive regulatory guidance from a recent meeting with the FDA regarding REMOXY.

Pain Therapeutics and the FDA met on February 13, 2017. During this meeting, agreement was reached on additional studies that are needed for REMOXY's approval. Pain expects to complete these studies by year-end 2017, at a cost of approximately $3-4 million. Following completion of these studies, Pain intends to have a pre-NDA meeting with the FDA, followed by resubmission of the REMOXY NDA, with anticipated Priority Review, under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Two requirements are needed for the resubmission of the REMOXY NDA:

- To conduct a clinical abuse potential study via the intranasal route of abuse; and
- To conduct a non-clinical abuse potential study using household solvents.

The intranasal clinical study will ask human volunteers to self-administer into their nostrils REMOXY, placebo or an active comparator. Positive data in one intranasal study is adequate to support a label claim against the intranasal route of abuse. Pain previously generated positive results using REMOXY under similar test conditions in a large animal model.

Pain will conduct a non-clinical abuse potential study in a lab using thin films of REMOXY smeared on glass plates to assess how household solvents affect the formulation. Pain plans to generate these data against comparator products. Positive data in this study is adequate to support a label claim against the injection route of abuse. Pain previously generated positive results using REMOXY under similar test conditions.

The discussions with the FDA did not raise any issues around safety, drug efficacy, manufacturing, stability or other drug development topics.

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 completed a **Phase III** study in Taiwan and anticipates obtaining top-line results from that study in the second quarter of 2017.

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.

Attractive Valuation

We continue to be optimistic about Durect story and raise our price target from $6.00 to $7:00 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 2019.

The company has initiated a new Phase III PERSIST trial with its clinical candidate Posimir. We estimate top line data will be available soon and the FDA approval will take place in 2018.

We are especially excited about the deal with Sandoz for Posimir which not only boosts the company's balance sheet but further validates the company's drug delivery technology and clinical program.

Based on our financial model, we expect the company will become profitable in 2020 with an EPS of $0.20 based on total revenue of $107 million, which include royalty revenue from Posimir and Remoxy, existing product sales and collaborative revenue. Based on this model, we come up with a fair value of the company at $4.00 per share, which values the company at $569 million in market cap based on 142 million outstanding shares.

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 epigenetic 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 $426 million in market cap based on 142 million outstanding shares, which is still conservative compared to its peers in our view.

Together our fair value for Durect is $7.00 per share, which values the company at $994 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 ($million)*
Intercept Pharmaceuticals, Inc.	ICPT	Phase II	$115.00	$2,860.00
FibroGen, Inc.	FGEN	Phase I/II	$29.00	$2,020.00
Raptor Pharmaceuticals Corp.	RPTP	Phase II	$9.00	$770.00
Average			**$51.00**	**$1,883.33**
DURECT Corporation	DRRX	Phase I/II	$1.10	$156.00

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	$5	$15	$30
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*100.0%*
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	$3.5	$4.2	$3.4	$15.2	$12.0	$12.0	$12.0
YOY Growth	*5.1%*	*4.6%*	*26.0%*	*-4.3%*	*7.6%*	*29.6%*	*25.6%*	*23.9%*	*22.3%*	*25.4%*	*-21.2%*	*0.0%*	*0.0%*
Collaborative Revenue	$0.4	$0.4	$0.4	$0.7	$1.9	$0.4	$5.0	$8.0	$8.0	$21.4	$25.0	$25.0	$50.0
YOY Growth	*-75.9%*	*-79.1%*	*-82.8%*	*-67.4%*	*-76.0%*	*3.6%*	*1247.7%*	*2172.7%*	*984.0%*	*1040.1%*	*16.6%*	*0.0%*	*100.0%*
Total Revenues	**$3.6**	**$3.2**	**$3.7**	**$3.5**	**$14.0**	**$4.6**	**$8.5**	**$12.2**	**$11.4**	**$36.7**	**$42.0**	**$57.0**	**$107.0**
YOY Growth	*-24.4%*	*-28.9%*	*-21.1%*	*-31.9%*	*-26.7%*	*26.6%*	*169.2%*	*225.9%*	*224.1%*	*161.4%*	*14.5%*	*35.7%*	*87.7%*
Cost of Goods Sold	$1.2	$0.9	$2.2	$1.0	$5.3	$1.5	$1.3	$1.5	$1.3	$5.6	$5.0	$5.2	$5.5
Product Gross Margin	*61.1%*	*67.2%*	*35.7%*	*65.6%*	*56.4%*	*62.7%*	*62.9%*	*64.3%*	*61.8%*	*63.0%*	*58.3%*	*56.7%*	*54.2%*
SG&A	$3.1	$2.9	$3.0	$2.8	$11.8	$3.0	$3.2	$3.3	$3.5	$13.0	$17.5	$22.5	$25.0
% SG&A	*84.9%*	*91.5%*	*81.3%*	*80.5%*	*84.3%*	*66.6%*	*37.6%*	*27.0%*	*30.7%*	*35.6%*	*41.7%*	*39.5%*	*23.4%*
R&D	$6.6	$7.9	$6.8	$8.0	$29.3	$7.5	$8.0	$8.5	$9.0	$33.0	$35.0	$40.0	$45.0
% R&D	*183.6%*	*248.7%*	*181.8%*	*227.2%*	*208.7%*	*165.3%*	*94.1%*	*69.7%*	*78.9%*	*90.1%*	*83.3%*	*70.2%*	*42.1%*
Operating Income	($7.3)	($8.5)	($8.3)	($8.3)	($32.4)	($7.6)	($4.0)	($1.1)	($2.4)	($15.1)	($15.5)	($10.7)	$31.5
Operating Margin	-	-	-	-	-	-	-	-	-	-	*-36.9%*	*-18.8%*	*29.4%*
Interest & Other Net	($0.5)	($0.5)	($0.5)	($0.5)	($2.1)	($0.5)	($0.5)	($0.5)	($0.5)	($2.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	($7.9)	($9.0)	($8.8)	($8.8)	($34.5)	($8.1)	($4.5)	($1.6)	($2.9)	($17.1)	($16.5)	($11.7)	$30.5
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)	($4.5)	($1.6)	($2.9)	($17.1)	($16.5)	($11.7)	$30.5
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*-29.1%*	*-360.7%*
Reported EPS	($0.06)	($0.07)	($0.06)	($0.06)	($0.26)	($0.06)	($0.03)	($0.01)	($0.02)	($0.12)	($0.11)	($0.08)	$0.20
YOY Growth					-					-	-	-	-
Shares Outstanding	122.1	132.8	137.9	139.6	133.1	141.8	142.0	145.0	146.0	143.7	147.0	150.0	155.0

Source: company filings and Zacks estimates

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