

### **Initiating Coverage**

November 24, 2014

TICKER	NASDAQ: REPH
RATING	BUY
PRICE TARGET	\$9.00
Price (November 21, 2014	\$2.68

## Recro Pharma, Inc.

From Worst in 2014 to First in 2015—Initiating With a Buy Rating and \$9 Price Target

Recro Pharma is a specialty pharmaceutical company developing an intranasal form of dexmedetomidine ("Dex") for the treatment of acute, post-surgical pain. There are nearly 50 million surgeries performed each year in the U.S. that cause acute moderate-to-severe pain, creating a \$3.4 billion branded-market potential.

As a pos-opioid based pain product. Dex-IN has the potential to reduce opioid-

As a non-opioid based pain product, Dex-IN has the potential to reduce opioid-related adverse events that are responsible for extending hospital stays and increasing the total cost of care for patients following surgery. Dex-IN utilizes a drug that has been approved and used safely in U.S. for 15 years as a sedative at 10X the dose planned for use in Dex-IN.

Trading at less than cash, a 30% discount to average cost of venture investor stock, and a 65% discount to its IPO price, Recro has been one of the worst IPOs of 2014. We think Recro is set for a dramatic rally on positive Phase 2b results and patent issuance in 2015. We rate the shares as a Buy with a \$9 price target.

Dex-IN Efficacy Demonstrated in Stable Pain Setting Prior to Recent Setback: The initial Phase 2b failed to show a significant benefit in patients with acute pain on the day of surgery, when pain is typically escalating to its highest levels. The second Phase 2b study is designed to measure effect when pain levels are either stable or declining on the days after surgery. The analgesic benefits of Dex-IN have already been demonstrated in short-term testing of chronic pain models. These patients have stable, consistent levels of pain and the positive results in this setting increase our confidence in the design of the ongoing Phase 2b.

Clinical Setback Can Be Quickly Overcome: Taking what was learned from the initial Phase 2b of Dex-IN in September, Recro has already initiated a second Phase 2b to confirm a signal it saw in a subset of patients from the initial study. The second study is focusing on a time course of treatment when pain has stabilized (Day 1 & 2) where the first was conducted when pain is not stable (Day 0 & 1). Interim results of the second study should be available in 1Q15 and final results by June 2015. Recro can easily reach these milestones with the cash currently available on its balance sheet.

**Dex-IN Patent Application Pending—May Be Issued in 2015:** Novel, non-obvious findings in earlier human studies are the foundation for a pending patent application. The application has been under review at USPTO for 23 months compared to the average review time of 29 months. As a result, we think the patent could issue in 2015, providing protection for Dex-IN through Dec. 2031. This could also be a significant catalyst for the stock.

We believe the stock is poised for a significant rally on positive news of Phase 2b clinical trial results for Dex-IN, potential patent issuance protecting Dex-IN and initiation of Phase 3 trials in late 2015. We think the present valuation gives investors an attractive risk reward with an estimated \$1 downside (based on expected cash burn) and potential upside of \$6-\$10 (based on DCF) for a stock currently trading below \$3. While far from riskless, we believe the option value is worthy of consideration. As such we are initiating coverage of Recro Pharma, Inc. with a \$9 target price based on our DCF model.

#### Market Cap (M): \$20.7 Shares out (M): 7.7 Float (M): 4.3 Daily Vol, 3 Mo Avg (M): 0.1 52-Week Range: \$9.88-\$2.63 Cash & Cash Eq (M): \$23.9 Debt (M): \$0.0 NAV (M): NA Short Interest (M): 0.0 Instit. Holdings (%): NA Cash Burn (M): \$10.2 Short Interest (% of Float): NA -3.67A -0.36A -0.61A -0.48E -2.83E 2014 2015 -0.56F -0.41F -0.36E -0.47F -1.80F 2016 -1.61E

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Lead Product Dex-IN targets acute post-surgical pain, a U.S. market with ≈50 million surgeries and branded potential of \$3.4 billion in 2014

Stock trades below cash, at a 30% discount to average cost for venture investors and 65% discount to the IPO price

Attractive risk reward with \$1 downside offset by upside potential of \$6-10 in the next 6-12 months

#### **Investment Thesis**

Recro Pharma is targeting a large market opportunity for the treatment of acute, post-surgical pain. Each year there are nearly 50 million surgeries performed in the U.S. that can cause moderate-to-severe post-surgical pain. Such pain has traditionally been treated with opioids that cause side effects, which can result in a prolonged hospital stay and significantly higher costs. Recent commercial success of Exparel from Pacira (PCRX, not covered) has demonstrated the ability of a non-opioid based product to succeed in the post-surgical, acute pain market. Since its launch in 2012, Exparel has experienced rapid sales growth and is on pace to exceed \$180 million this year (third full year on the market).

product Dex-IN, an intranasal formulation dexmedetomidine, could tap into the need for non-opoid based pain products that can provide effective treatment of acute pain following surgery. While Exparel has been very well received it can only be administered during surgery, is only truly effective during the first 24 hours following surgery, and cannot be readministered. This leaves open an opportunity for a drug like Dex-IN that can provide a benefit in the days following surgery without the adverse events and safety concerns associated with currently approved opioids. With the potential to receive a broader label (Exparel label is limited to two types of surgeries) and to be used for a longer period of time, including days following discharge, Dex-IN is positioned to take share from opioids that currently dominate this market. Dex-IN can generate \$150-\$200 million in annual sales by capturing just a 4%-5% share.

Trading near \$2.70, the stock trades below cash (\$3.10/share), at a 30% discount to the average cost of shares (\$4) for its founder & venture investors, and a 65% discount to its \$8 IPO price. We believe this makes Recro all the more attractive at current levels. Using our DCF-based valuation analysis (see Valuation discussion below) and anticipated cash burn, we think the stock has \$1 in downside risk and upside potential of \$6-\$10 in the next 6-12 months.

As a result, we are initiating coverage with a Buy rating and \$9 PT.

#### **Catalysts**

Recro is set to rapidly enroll, analyze interim data, and complete its Phase 2b study of Dex-IN by June 2015. Dex-IN is an intranasal formulation of dexmedetomidine, which has been used safely as an IV sedative (Precedex) in the U.S. for 15 years at a dose as much as 10X higher than the one used in Dex-IN. We believe the stock is

oversold as a result of the inital Phase 2b study, which was halted early when an interim analysis revealed the study was not likely to show a significant benefit in the first 48 hours (Day 0 and Day 1) after surgery. The second Phase 2b study is measuring pain relief over 48 hours starting the day after surgery (Day 1 & Day 2), when pain levels have stabilized, rather than the day of surgery when they can be quite high and variable. The second Phase 2b is designed to confirm efficacy—seen in earlier studies of patients with chronic pain who had stable pain levlels and the trend toward pain relief seen in a subset of patients with less severe pain in the initial Phase 2b—by demonstrating pain relief in paitents whose pain has stablized after surgery.

A similar approach was used by Cadence Pharmaceuticals (subsequently acquired by Mallinckrodt: MNK, not covered) for Ofirmev, following a failure of a Phase 3 trial to show a benefit when treating hysterectomy patients immediately after surgery and measuring pain intensity on Day 0 & Day 1. The company repeated the Phase 3 trial in patients having a hysterectomy or gall bladder surgery, but limited the trial to those with moderate pain on the morning after surgery (Day 1). This second trial succeeded using the same dose for which the earlier study had failed to show a benefit. As a result, Ofirmev, an intravenously administered formulation of acetaminophen, is now FDA approved and currently marketed with an annualized revenue run rate in excess of \$200 million.

2015 Catalysts include interim and final results of Phase 2b, potential patent issuance and initiation of Phase 3 trial(s) Recro can rapidly progress from development to commercialization in three years. Like the Phase 2b study, the Phase 3 studies would likely be enrolled and completed in just 9 months, setting Recro up to file an NDA on Dex-IN in early 2017 and receive approval to launch by late 2017 or early 2018.

Our confidence in Recro's ability to quickly navigate clinical and regulatory hurdles, needed to progress to commercialization, is supported by a strong track record of management. Recro was founded and continues to be led by Gerri Henwood, the former founder and CEO of Auxilium (AUXL, not covered). Gerri led Auxilium to a market capitalization in excess of \$1 billion by rapidly executing the clinical development of Testim and gaining FDA approval on first review. She then led the successful launch of Testim into a market dominated by an established competitor that was first to bring a topical testosterone gel to market. Prior to Auxilium, she founded IBAH, a publicly-traded contract research organization that designed, conducted, and analyzed clinical trials for other pharmaceutical firms. During her leadership IBAH prepared 48 new drug applications for it clients. It was during her time at IBAH that Gerri first worked with Dex and saw its potential for other uses.

De	Dex-IN Milestones to Launch											
Qtr/Yr	Qtr/Yr Month Milestone											
1Q15	Feb/Mar	Phase 2B Interim Analysis										
2Q15	June	Phase 2B Top-Line Results										
2015	TBD	USPTO Patent Allowance for Dex-IN										
4Q15/1Q16	TBD	Initiate Phase 3 studies										
3Q/4Q16	TBD	Report Phase 3 topline results										
1Q/2Q17	TBD	NDA submission										
4Q17/1Q18	TBD	FDA Approval										
Mid 2018	TBD	Commercial Launch										
Source: Company reports, clinicaltrials.gov, and MLV Research Estimates.												

#### **Valuation**

The success of two non-opioid based products to treat post-surgical pain in recent years gives us confidence in the prospects for DEX-IN. The two products are Pacira's Exparel, which is injected or infiltrated in the wound site prior to closure during surgery to provide pain relief on the day of surgery (Day 0) but not beyond; and Ofirmev, intravenously administered acetaminophen, that has a broader label to include the treatment of mild-to-moderate pain or as an adjunct to opioid analgesics. While both had slow first year sales (≤\$15 mln) due to the need to obtain inclusion on hospital formularies, sales in subsequent years have grown significantly. Ofirmev exceeded \$100 million in sales during its third full year on the market in 2013 and Exparel is on pace to generate nearly \$200 mln in sales in 2014, its third full year on the market. As an intranasal product Dex-IN can be used in a hospital, or at home, by a patient following surgery, thereby positioning it as a non-opioid, post-surgical pain product that can easily be used for several days after surgery. This creates the potential for a longer period of use (Day 1, 2, 3, etc.) than either of these existing products.

Using Ofirmev's 3.5% share of the market for intravenously administered pain products (based on vials), or 7% penetration for the post-surgical acute pain market (based on estimated number of patients treated) we believe a 4%-5% penetration rate for Dex-IN is reasonable. Consequently we think Dex-IN could approach \$100 million in sales in 2020 and easily reach \$200 million in sales by 2022.

Recro is positioned to rapidly transition from significant losses during the drug development and early commercialization phase, to high levels of revenues, earnings and cash flows in five years. Using a 14% discount rate—which is just below the 14.5% discount rate presently implied for biotechnology companies and significantly

Dex-IN could reach the market by 2018, approach \$100 mln in sales in 2020 and exceed \$200 mln in 2022

With catalysts next year DCF valuation moves from \$9 today to a level approaching \$13 a year from now greater the than the 10% and 8% implied for more mature pharmaceutical companies and the broader market, respectively—the stream of future cash flows is worth \$140.6 million. Comparing the DCF value to Recro's current market cap of \$21 million the potential valuation disparity becomes very apparent. Even after factoring in 100% dilution, which we estimate to be required to fund completion of development and to support early commercial efforts, Recro still justifies a DCF/share valuation of \$9.

We believe the stock is poised for a significant advance next year on news of positive Phase 2b clinical trial results for Dex-IN, possible patent issuance protecting the product out to 2031, and initiation of Phase 3 trials. The risk-reducing benefits of these events would further increase our valuation from \$9 today to a level approaching \$13 a year from now.

Trading below cash, we think the present valuation gives investors an attractive risk reward proposition with \$1 downside (based on expected cash burn) and potential upside of \$6-\$10 for a stock trading below \$3 per share. While far from riskless, we believe the option value is very attractive. As such we are initiating coverage of Recro Pharma, Inc. with a \$9 target price based on our current DCF/share valuation.

#### **INVESTMENT RISKS**

Clinical Trial Risk — Dexmedetomidine is approved for sedation in countries around the world but has never been approved for pain relief, or in an intranasal form. Drug development is a risky business that is speculative in nature. Failure in clinical trials, regardless of the stage of development, can cause significant volatility and may reduce a company's ability to raise needed capital, or to remain in business.

**Funding Risk** —As a microcap, drug development stock, Recro carries significant funding risk. If Phase 2b, or Phase 3 study are not positive for Dex-IN, it could be difficult, or even impossible, for Recro to raise the capital needed to develop its pipeline.

**Dilution Risk** — An investment in a drug development company carries dilution risk, the only question is how much? The biggest dilution risk that can occur is a sizeable offering under unfavorable market conditions, or worse, in conjunction with adverse company news.

**Regulatory Risk** —Even with successful clinical trials, the regulatory review process is rigorous and can result in substantial delays, need for further pre-clinical or clinical studies, and is not a guarantee of approval. FDA may determine the drug's risk/benefit does not favor

Investing in drug development companies involves a high degree of risk and should be considered speculative

patients, or see safety concerns from other products that could hinder or prevent approval.

**Supplier Risk** — Recro's API supply and nasal pump supplier are provided separately by single sources. Failure of suppliers, or contract manufacturers, to maintain quality manufacturing practices in accordance with FDA standards would have significant negative implications for Recro. If this were to occur during FDA review, it could result in a complete response letter that Recro may not satisfy until it finds and qualifies alternative suppliers or its existing suppliers regain compliance with FDA standards.

Commercial Risk — Even if Recro is able to gain FDA approval for Dex-IN, it still carries commercial risk of failure. The effort required to build out a 50-60 person sales organization would likely cost the company \$15-\$20 million on an annual basis. This along with other launch-related expenses are likely to exceed the costs of development for Dex-IN. As such, the inability to generate a meaningful level of sales (e.g. >\$30 million) could result in ongoing financial burden to the company that would divert capital resources from other development efforts. Alternatively, the inability to adequately fund its selling effort could cause the company to fall well short of sales expectations implied by our estimates.

Intellectual Property Risk — Recro currently does not have patents protecting its formulation of Dex-IN or the intranasal use of Dex to treat pain. Absent patents, the company would only be eligible for three years of exclusivity before a generic product could be approved and launched. Recro has patents pending at the U.S. Patent & Trademark Office, but failure to secure a patent would have significant negative implications for our model and the long-term prospects for DEX-IN.

#### **Market Opportunity**

Each year there are ≈50 million surgeries performed in the U.S. that can cause moderate-severe post-surgical pain Surgical procedures are performed either on an out-patient basis, where the patient is ambulatory post-surgery and able to return home the same day of surgery; or, on an in-patient basis, requiring admission to a hospital. The National Hospital Discharge Survey (2010) and the National Survey of Ambulatory Surgery track about 100 million procedures that take place each year at hospitals or ambulatory surgery centers. However, many of the procedures captured by the data are diagnostic in nature (e.g. endoscopy, CAT scan, cardiac stress test, etc.) or involve low levels of post-procedure pain (e.g. cataract or LASIK surgery). There are nearly 50 million surgeries (table below) performed each year for which a post-operative pain medication is needed to treat moderate-to-severe pain.

At branded pricing the market to treat post-surgical pain should grow from \$3.4 billion in 2014 to \$4.7 billion in 2022

Dex-IN could achieve \$150-\$200 million in sales with just 4%-5% market share It is too early for Recro to talk specific pricing plans for Dex-IN, but we think it is reasonable to assume it will be priced comparable to branded oral opioids that are often used to treat pain in the days after surgery. With this in mind we examined the cost of Opana, which is priced at \$7/tablet for (10mg) and requires 4-6 pills at the lowest dose (10mg) and twice as many at the upper end of the initial recommended dose (20mg) for a day's worth of therapy. In other words, the daily cost of Opana treatment could range from \$28-\$42 for low dose and \$56-\$84 for the higher recommended starting dose. With the potential to treat patients for more than one day, we are using a price for Dex-IN on a per patient basis of \$70. This is equivalent pricing to 2-3 days of the lowest possible dose of Opana or about 1 day at the higher dose. Clearly, whether compared to other non-opioid alternatives in the market for acute post-surgical pain (such as Ofirmev and Exparel) or to oral opioids it would be displacing (such as Opana), we think this assumption is conservative for a starting price three years out. With modest (3%) price inflation, the value-per-patient treated with Dex-IN would rise to about \$90 in 2022.

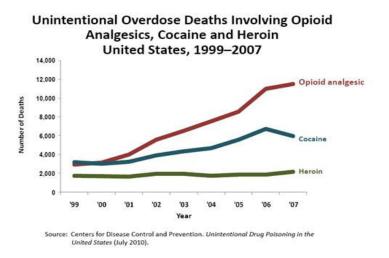
Using these conservative revenue assumptions on a per-patient basis and applying it to the total market, we believe the branded value of the U.S. market for products to treat acute post-surgical pain is currently \$3.4 billion and can be expected to grow to around \$4.7 billion in 2022. Actual sales of Dex-IN, or other competitors in the space, are likely to be a fraction of this figure. Yet, with just 4%-5% share of the post-surgical acute pain market, a product like Dex-IN can still reach annual sales in the range of \$150-\$200 million. Compared to the broader market for analgesic medications, such use would still account for less than 1% of annual analgesic prescriptions filled in the U.S. Comparable adoption rates, or sales levels, of products in this segment has already been demonstrated by the launches of Ofirmev in 2011 and Exparel in 2012 (see "Competitive Market Implications" below).

CommonSurgical Procedures	Inpatient	<b>Ambulatory</b>
Operations on Nervous System (excludes spinal tap)	940,000	1,178,000
Operations on Nose, mouth and pharynx	281,000	2,864,000
Operation on Respiratory Sys. (excl. bronchoscopy)	1,008,000	272,000
Operation on Cardiovascular Sys. (excl. cardiac catherization)	6,425,000	884,000
Operations on Hemic & Lymphatic Sys.	418,000	344,000
Operations on Digestive Sys. (excl. endoscopy)	4,421,000	3,807,000
Operations on Urinary Sys. (excl. cystoscopy)	1,047,000	1,025,000
Operations on Male Genital Organs	218,000	631,000
Operations on Female Genital Organs	1,609,000	2,497,000
Operations on Musculoskeletal System	5,561,000	7,944,000
Operations on Integumentary Sys. (a.k.a skin)	1,484,000	3,561,000
Total	23,412,000	25,007,000
Total Inpatient Surgery	23,4:	12,000
Total Outpatient Surgery	25,00	07,000
Total # of Surgeries with Moderate-to-Severe Pain	48.43	19,000

Despite risks of opioid diversion and abuse that have led to more than 10,000 deaths annually in U.S., opioids are prescribed for >90% of postoperative patients due to a lack of effective alternatives

### **Movement Away from Opioids Due to Abuse and AEs**

For those unfamiliar with the issue of prescription drug abuse, it is difficult to envision the scale and scope of the problem just as much as it is to understand the reasons for its emergence as a major public health concern. In 2008, the FDA made the case that the launch of Oxycontin is the root cause for the problems over the past 16 years. At the FDA's Advisory Committee meetings to consider new tamper resistant formulations in 2008, that message was pounded home. The statistics show a clear correlation in the rise of prescriptions of Oxycontin being associated with increased emergency room visits involving opioid analgesics and a sustained increase in opioid-induced overdose resulting in death. problem of drug-induced deaths is a well-known risk that most in older generations associate with illicit drug use (heroin, cocaine, etc.). However, as the chart below makes clear, the rapid rise in drug-induced deaths seen in the last decade is primarily linked with abuse of prescription pain killers.



#### Opioid-related AEs May Cost up to \$65 Billion Annually

A significant portion of Exparel's success stems from the measurable reduction in post-surgical use of opioids that its use can provide. This is important because a study involving the examination of more than 300,000 patient records has shown that patients who suffer from opioid-related adverse events have an increased length of stay and an associated increase in total cost of care. A subsequent study sponsored by Pacira confirmed these results with more detail. The study looked at records of 26 hospitals and showed that 98.6% of patients hospitalized for a surgical procedure received opioids following surgery, and of those, 13.6% had some form of opioid-induced adverse event that typically results in a longer stay and higher cost (about \$10,000 higher). Applying this data to the U.S. it

Dex-IN, as a non-opioid, should avoid Opioid-related Adverse Events (AEs) contributing to its commercial appeal

would appear that avoiding opioid-related adverse events has the potential to save payors nearly \$65 billion each and every year.

## Avoiding Opioids May Reduce Re-admission Risk and Associated Penatlites

We believe the non-opioid approach of Dex-IN offers a clear advantage to opioids in the hospital market where Medicare is now penalizing hospitals for patients who return within 30 days of discharge. A Pacira study also showed that patients who suffered from an opioid-related adverse event were 36% more likely to be readmitted to the hospital in the next 30 days. While Exparel provides a significant benefit in the first 24 hours after surgery in reducing pain, its benefits diminish significantly after 12 hours and it cannot be readministered post-surgically. For those whose pain continues beyond the first 24 hours a product like Dex-IN, which can be given in the hospital and sent home with the patient on discharge, would be an added benefit.

Patients with Opioid-related AEs are 36% more likely to be readmitted to the hospital, which can trigger financial penalties from Medicare

Avoiding the higher risk of readmission can protect the hospital from signficant financial penalties enacted under federal law. Under provisions of the Affordable Care Act that went into effect in October 2012, Medicare is required by law to penalize hospitals that have rates of readmission outside of specified standards. Medicare has determined that last year 18% of previously hospitalized patients returned to the hospital within a month. Those hospitals with high readmission rates (2,610 most recently, or about 75% of those for which these requirements apply) have been penalized under the new law. The penalties, which in total are expected to aggregate to \$428 million. The penalty for each hospital varies from a fraction of a percentage to 3% of each payment received from Medicare on all admissions for the next full year.

# **Dex-IN Offers Significant Advantages and Alternative to Opioid Pain Medications**

Recro's Dex-IN offers an alternative to opioids in a wide array of moderate-to-severe pain indications and could offer physicians a way to avoid concerns about the risk of dependence and abuse that exist with opioids. In spite of huge safety concerns regarding the abuse potential of opioids, they remain the primary pharmaceuticals of choice when it comes to treating moderate-to-severe pain. According to IMS Health, in 2013, opioids accounted for 53% of all prescription pharmaceuticals for pain management. In the post-surgical, acute pain market the use of opioids appears to be as high as 98.6% and consistently referenced as being in excess of 90%.

Dexmedetomidine ("Dex") has a 15-year history of safe and effective use in the U.S. as a sedative

Dexmedetomidine ("Dex") is a non-opioid drug that has demonstrated sedative, analgesic, and anxiolytic properties. Recro intends to develop and gain FDA approval for Dex-IN for postsurgical pain by changing the route of administration of Dex from intravenous infusion to intranasal at about 1/10 the dose. Dex was initially approved for use in the United States under the brand name Precedex; however, the composition of matter patent protecting Dex expired in January 2014 (for IP information on Dex-IN, see "Non-Obvious Clinical Findings Key to Dex-IN Patent that Could Issue in 2015"). The drug has a long history of use for its first indication, "sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting". More recently the indication was expanded to include "sedation of non-intubated patients prior to and/or during surgical procedures". Hospira (HSP, not covered) generated \$368 million in U.S. sales for Precedex last year before entry of generic versions of this IV product were cleared by the courts to enter the market in late 2014.

## The advantages of Dex relative to opioids includes the following:

- Dex does not cause addiction, based on studies conducted for Precedex
- Dex does not cause respiratory depression, which is major safety concern for opioids
- Dex is not associated with common opioid side effects including constipation, nausea and vomiting. In fact, in the Phase 2a study only 31% of patients treated with 50mcg of Dex-IN experienced nausea or vomitting compared to 63% on Placebo.
- Intranasal administration avoids the risk oral products have of exacerbating sypmptoms of nausea and eliminates uncetainty about what to do if a paitient vomits after taking an oral medication for pain.
- Dex has been shown to lower morphine requirements to manage pain, whereas opioid dependent patients require increasing doses to maintain adequate pain relief. From our perspective, even if Dex cannot completely replace opioids for patients with severe pain, it could be used in conjunction with opioids to reduce the dose necessary to adequately manage their pain. The Precedex label specifically speaks to this potential in the following statement, "Co-administration of Precedex with anesthetics, sedatives, hypnotics, and opioids is likely to lead to an enhancement of effects."

As a non-opioid Dex-IN avoids risks of addiction and opioid-related adverse events. Even if not effective enough to eliminate opioids there is evidence that Dex-treated patients require less opioids for effective pain relief

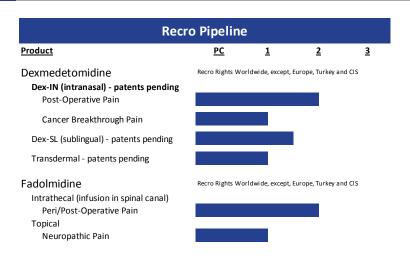
#### Typical side effects/disadvantages for Dex include:

- Somnolence, or drowsiness, which is no surprise for a product that at higher doses is used to cause sedation. Yet in the Phase 2a trial the rate of drowsiness for 50mcg Dex-IN was not different from placebo.
- Dex is known in sedative doses to cause hypotension, or a greater than 30% drop in blood pressure. Recro has seen decreases in blood pressure in about 40% of patients treated with the 50mcg dose of Dex-IN.
- Most patients have a decrease in blood pressure that is measurable but occurs without symptoms. However, in some cases the hypotensive effects were noticed by patients and resulted in discontinuation. We expect blood pressure effects may cause up to 10% of patients to be discontinued from therapy. By comparison, droupouts in other opioid-related pain trials often result in much higher rates of discontinuation due to adverse events (≈25%) such as nausea/vomitting and constipation.
- Most importantly in the latest Phase 2, which has been the largest clinical study of Dex-IN to date (n=95), there were no serious adverse events reported.
- One disadvantage of Dex-IN, relative to opioids, appears to be less effectiveness in patients with high levels of pain. This suggests that in patients with the most severe pain, treatments with opioids may still be needed. As discussed in advantage section, there is still evidence that Dex reduces the amount of opioids required in such circumstances. This will need to be confirmed with Dex-IN before it is likely to be used in patients with severe pain (e.g. >7 on a 0-10 scale with 10 being worst pain imaginable).

Through its license with Orion Group, Recro will be able to reference the existing preclinical and clinical data used in the NDA for Precedex when it files an NDA for any of its Dex-based products (see Pipeline Table Below). The studies used to gain regulatory approval in the U.S. and EU for IV dexmedetomidine include a safety database of 4,765 Dex-treated patients. Importantly, these studies included doses of Dex much higher than that used in Dex-IN. Recro has seen no serous adverse events to date and there have no signs of ECG abnormalities (such as QT prolongation) in the data. As such we believe Dex-IN offers a less risky and less costly path to market than a new molecular entity.

Dex's potential to reduce blood pressure is well known and should be manageable in the vast majority of patients

Although Recro has two compounds and multiple formulations in development, its efforts are entirely focused on development of Dex-IN



Challenges of failed pain studies not unusual in products that have gone on to gain FDA approval and enjoy commercial success

Initial Phase 2b revealed benefits in a subset of patients with moderate and stable pain

#### **Reasons for Confidence in Dex-IN**

#### Path to Approval in Pain Indication Rarely a Straight Line

History of Failed Studies in Pain Indication before Gaining FDA Approval—Clinical failures are disappointing and can lead to the termination of a clinical program; but, there are many examples of failed studies for pain products that ultimately went on to gain FDA approval. Thus, failure to demonstrate efficacy in a clinical trial for a product to treat pain does not necessarily spell disaster, as it may in other indications. In fact, there is a long history of products that have gained FDA approval for a pain indication that have at least one failed study of efficacy during development (including Ofirmev and Exparel).

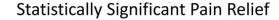
What is Learned from Failed Results of Phase 2 Study of Dex-IN? The results of the first Phase 2b study of Dex-IN in an acute pain model showed mixed results. On the one hand, the study showed that Dex-IN was not effective enough to treat severe post-surgical pain (baseline pain intensity score >6) on the day of surgery when pain is on an increasing trajectory. As a result, the study failed to show a difference from placebo in SPID48 (summed pain intensity difference over 48 hours) when measured on the day of (Day 0) and day after surgery (Day 1). On the other hand, a subset analysis of patients (about 50%) with more moderate pain at baseline (baseline intensity score of ≥4 and ≤6) appeared to see some benefit with treatment from Dex-IN. Recro has changed the treatment and measurement period (from Day 0-1 to Day 1-2) with the belief that Dex-IN will more effectively treat stabilized pain that exists the day following surgery as opposed to the escalating pain that exists on the day of surgery.

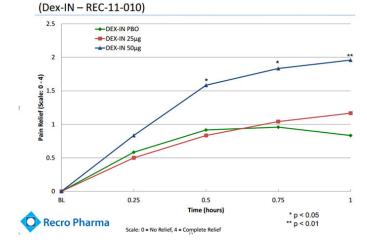
A similar approach was used by Cadence Pharmaceuticals (subsequently acquired by Mallinckrodt: MNK, not covered) for

50mcg Dex-IN has proven to be highly effective at relieving pain in patients with stable pain scores. This increases confidence in likelihood of positive outcome in ongoing Phase 2b study for treating acute-post surgical pain

Ofirmev during its development. Ofirmev failed to show a benefit in a Phase 3 trial when treating hysterectomy patients immediately after surgery and measuring pain intensity on Day 0 & Day 1. The company repeated the Phase 3 trial in patients having a hysterectomy or gall bladder surgery, but limited enrollment to those patients with more moderate pain on the morning after surgery (Day 1). This second trial succeeded using the same dose for which the earlier study had failed to show a benefit. As a result, Ofirmev is now FDA approved.

Prior study provides support for view that DEX-IN is effective in patients with stable pain. Although Dex-IN hit a snag in the first Phase 2 study in acute post-surgical pain earlier this year, confidence in the analgesic effect of Dex-IN in a stable pain model is bolstered by results of an earlier Phase 2 study of Dex-IN in patients with chronic lower back pain. This study, referred to by Recro as REC-11-010 examined 24 patients in a 3-way crossover of placebo, 25mcg of Dex-IN and 50mcg of Dex-IN.





50mcg Dex-IN appears to be the lowest effective dose and is the focus of ongoing Phase 2b Based on the data from a study of chronic lower back pain, 50mcg of Dex-IN has proven to provide statistically significant pain relief (within 30 minutes) compared to placebo in patients. This data provides support for expected efficacy in patients with stable levels of moderate-to-severe pain. Post-surgical patients' pain scores tend to stabilize or decrease on the day after surgery. As a result, Recro has changed the measurement period for pain relief (primary efficacy endpoint) from Day 0 & Day 1 in the initial study in post surgical pain, to Day 1 & Day 2.

The results of the chronic back pain study indicated that 25mcg of Dex-IN did not provide adequate pain relief and in the Phase 2b acute post-surgical pain study, the same appeared to be true for the 35mcg dose. It appears the 50mcg dose is the lowest effective dose that has been studied to date. As a result, Recro is focusing its

Ongoing Phase 2b has far greater power to demonstrate a meaningful difference than the initial Phase 2b

Finding that single nostril administration provided better Cmax and Tmax than half the dose administered to each nostril is an important, non-obvious discovery we expect to be key to receiving patent that effectively protects Dex-IN from generics until 2031

efforts on the 50mcg dose for the ongoing Phase 2b study and planned Phase 3 studies.

The ongoing Phase 2b study will compare 50mcg of Dex-IN to Placebo in a study with planned enrollment of between 200-250 patients following bunionectomy surgery. This is larger than the initial Phase 2b which was scheduled to enroll 150-200 and halted after interim analysis of first 75 patients. Like the first Phase 2b, Recro plans an interim analysis at approximately 50% enrollment. The interim analysis should provide far greater power to reveal a treatment difference than the first study due to larger total numbers (interim n=75 vs n=100-125) and the fact that there are just two treatment arms instead of three. At the interim analysis there will be nearly as many patients in each treatment arm (n=50-63) as there were across all three arms of the initial study.

We turn our attention next to how Recro can defend the commercial prospects for Dex-IN when the underlying molecule lost its patent protection in 2014.

# Non-Obvious Clinical Findings Key to Dex-IN Patent that May Issue in 2015

Questions around intellectual property protection are always raised when a company's products under development include existing active pharmaceutical ingredients (API) as opposed to new chemical entities. The API in Recro's lead product under development is dexmedetomidine, the active ingredient in Hospira's IV formulation of dexmedetomidine (Precedex), which now faces generic competition. Recro is developing an intranasal formulation of dexmedetomidine, or Dex-IN, for the treatment of pain following surgery. The clinical trials necessary to gain approval of Dex-IN for this indication would qualify for three years of market exclusivity under FDA's definition of "new clinical investigation". Based on discoveries made during initial human PK testing of Dex-IN, we expect Recro to receive patent protection for Dex-IN that will significantly extend exclusivity beyond the three years provided by the FDA for "new clinical investigations". The findings quoted below are directly from the patent application.

"The pharmacokinetics observed showed the surprising result that the administration of the dose in single spray to a single nostril (Treatment B) provided a better C.sub.max and a shorter T.sub.max as compared to the same total dose administered in two nostrils via 2 sprays (half the dose being administered into each nostril). This result could not have been predicted and is opposite of what would have been expected by the skilled artisan, in part, due to a surface area

to a single nostril can facilitate the more rapid onset of activity (e.g., pain relief) in target patient populations. The rate of absorption observed in Treatment B was more rapid than previously studied non-IV formulations or routes of administration. This unexpected more rapid absorption can allow for the fast onset of analgesic effects."

The patent application was submitted December 12, 2012 and

Dex-IN patent has been under review at USPTO for 23 months compared to 29 month average review time

claims priority under a provisional application that was submitted to the U.S. Patent Office on December 11, 2011. The patent application is still being prosecuted with the U.S. Patent Office and would be eligible for exclusivity until December 11, 2031 if issued. Recro anticipates patent prosecution to be completed before they are prepared to submit the NDA for Dex-IN to the FDA. In other words it should come no later than 2016.

comparison. The mean plasma concentrations produced by Treatment B reached a minimum target concentration (0.1 ng/ml) within 20 minutes after dosing. This surprising result of administering

We think Dex-IN patent will receive notice of allowance in 2015, an achievement that should serve as a catalyst for the stock An examination of USPTO Performance and Accountability Report indicates patent review times have been consistently shrinking over the past few years—from 35 months in 2010 to 29 months in 2013. Based on these figures, we think this patent could issue next year. The non-obvious findings described above are likely to be an important element of the Patent Office's final determination regarding the patentability of Dex-IN. It will also be key to defending patent litigation that is likely to come from generic filers if the product is approved by the FDA.

Recro is also attempting to gain patent protection for a sublingual formulation of dexmedetomidine, or DEX-SL. A review of the patent application for DEX-SL did not reveal unexpected findings from studies of the formulation. Currently Recro is in the process of appealing a final objection by the patent examiner that is preventing the allowance of the claims. Recro is appealing the examiner's decision to the Patent Trial and Appeal Board. If the examiner's decision is reversed and the patent is allowed, then it would provide protection of DEX-SL until May 15, 2029 and likely open the door to further clinical studies. Recro has targeted DEX-SL for chronic pain indications.

We are confident in Recro's ability to secure at least one patent protecting Dex-IN Through Dec. 2031.

### **Competitive Market Implications**

#### **Route of Administration Affects Duration of Use**

Ofirmev is in intravenously administered acetaminophen product used alone to treat pain, as an adjunct to opioid analgesics, and to treat fever. It was the first of two recently approved non-opioid-based products intended to treat acute post-surgical pain without the risks and complications of opioid related analgesics (see "Movement Away from Opioids Due to Abuse and AEs" section for more detail). A point made clear by its tag line "Less pain. Less opioids." While there is no limitation for use on the label, its intravenous delivery does create practical limitations to Ofirmev's use.

Ongoing Phase 2b is testing Dex-IN effectiveness in Day 1 & Day 2 pain relief. This means it can be used after surgery while Exparel is only proven to be effective on the day of surgery (Day 0) and cannot be used on subsequent days.

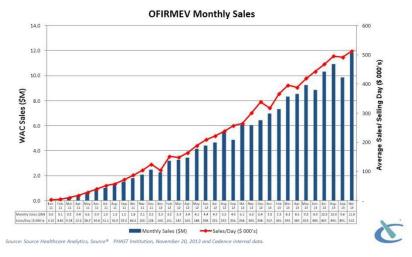
Thus, Ofirmev is used for relatively short duration of treatment compared to what we anticipate for Dex-IN. The typical Ofirmev patient is treated with 2-2.5 vials, suggesting an average period of treatment for an adult of at most 12-16 hours. Hence it would appear Ofirmev's use is limited to the day of surgery as an alternative, or adjunct to, morphine in patient controlled analgesia on the day of surgery. Removing a patient from IV treatments and stabilizing their pain prior to discharge is a critical step in the post-surgical market. During this time patients on Ofirmev would be switched to other products at discharge (in an ambulatory setting) or prior to discharge (in an in-patient setting). Such a switch would not be necessary for Dex-IN opening up the potential for a longer period of use of Dex-IN than has been the case with Ofirmev.

The longer potential treatment period for Dex-IN has potential financial implications relative to Ofirmev. At launch, Ofirmev was priced by Cadence at roughly \$10.75/vial, suggesting a per-patient-value of \$21-\$27. After Cadence was acquired, Mallinckrodt increased the price per vial for Ofirmev by 2.4X to about \$35/vial. This pushed the per-patient-value to \$70-\$90 for Ofirmev. As mentioned above, this is for less than a full day's treatment of pain. A full day of treatment would cost \$140 for Ofirmev. While much higher than its launch price, this still appears cheap compared to Exparel, which is priced at \$285/vial and provides up to 24 hours of pain relief following surgery. Even at a discounted rate, compared to alternatives on a revenue-per-day of treatment, Dex-IN could still generate comparable per patient revenue as a result of its potential to treat patients for multiple days.

#### Ofirmev - Priced Too Low at Launch?

Cadence put a significant effort into the initial launch of Ofirmev that in retrospect may not have paid the dividends it initially had hoped to receive from such effort. The Ofirmev launch was supported by 147 hospital sales specialists, or about 2.5X bigger than the sales force used to launch Exparel by Pacira a year later.

Despite the heavy promotional effort, the need to secure a position on hospital formularies created a common challenge for both companies in the first year of sales. As the graph below demonstrates, Cadence effectively booked no sales (\$0.3 mln) during the first three months of launch and the second quarter of launch was not much better (\$1.9 mln). Thus, while the company booked \$11.5 million in first year sales for Ofirmev, more than 50% was generated in the fourth quarter. From a sales perspective this is less than Pacira managed to accomplish a year later (\$14.7 mln) with a sales organization that was about 1/3 the size.



Source: Cadence Pharmaceuticals Dec. 2013

While Ofirmev has seen far greater uptake in terms of units and patients treated relative to Exparel, it is Exparel that has come out on top with regard to total revenues generated. Exparel has made up for the lack of volume by using a premium pricing initiative that results in its cost per day of treatment being \$285 compared to roughly \$43 per day for Ofirmev at launch.

At launch, Cadence was concerned about pricing of its product relative to Caldalor, a branded IV ibuprofen product that was approved in 2009. With its lower price strategy and aggressive effort with a much larger sales force, Cadence was able to capture a meaningful share (3.5% based on IV analgesic vials and 7% based on an estimate of treated patients) of this market.

Sales and Marketshar	e (Ofirn	nev)	
Ofirmev Sales	\$11,486	\$50,066	\$110,529
Vials of Ofirmev (est.)†	1,200	4,900	8,892
Market share based on vials †	0.44%	2.0%	3.5%
Patients (est. based on 2-2.5 vials* per patient)†	480	1,960	3,557
Market share based on surgical patients †	1%	4%	7%
*Cadence Presentation June 2012	† MLV & CO E	stimates	

Clearly management of Mallinckrodt felt the price of Ofirmev was too low. Surely this view was helped in part by the success of Exparel described in more detail below. Subsequent to acquiring Cadence, Mallinckrodt raised the price on Ofirmev by 140%. Initially volume decreased by 20%, suggesting that total sales still grew significantly despite the reduction in volume. The shift in pricing strategy enabled Mallinckrodt to generate \$53.2 million in Ofirmev sales during 2Q14, or nearly equal to 50% of total sales for Ofirmev in 2013. The new pricing strategy puts Ofirmev on pace to easily generate \$200 million, or more, next year.

In Europe, the introduction of IV acetaminophen (IV-APAP) resulted in a dramatic shift away from injectable/IV opioids to the non-opioid alternative, IV-APAP. In a five year span between 2004 and 2009, IV-APAP increased from 2% of the IV analgesic market to 35% while the share of IV opioid analgesics declined from 89% to 63%. This points to the significant potential for non-opioid based products to take share from opioids that have long dominated the market for acute post-surgical pain.

#### Exparel "Extra" Potential in Post-Surgical, Acute Pain Market

Pacira (PCRX, not covered) went public at \$7 per share in February 2011. At the time of the IPO, Pacira had an NDA pending for Exparel, a proprietary liposomal injection that provides extended-release bupivicane applied locally in the surgical wound during the procedure. Bupivicane was a well known non-opioid analgesic, whose use was limited by the fact that it only provided pain relief at the wound site for less than 7 hours. Exparel has been shown to reduce pain during the first 24 hours after surgery and to reduce the post-surgical use of opioids for pain relief. FDA approval of Exparel in October 2011 led to its launch in January 2012.

The stock traded as high as \$19 in first year of commercialization when sales reached only \$14.7 million; however, the stock took off once hospital formulary coverage increased and physcians gained comfort with its use. Importantly, Pacira was able to cover 80% of its target market with a 60-person hospital specialty sales force.

Exparel launch supported by 60person sales force shows potential for meaningful impact from small commercial effort

Exparel on pace to generate \$190 million, on less than 2% market share, in third full year on the market

Sales and Mark	etshare	(Exparel)	
<u>Year</u> Sales (M) <u>Vials</u>	<b>2012</b> \$14.70 51,578	<b>2013</b> \$76.10 267,017	<b>2014</b> \$189.94 666,456
Buionectomies Hemorrhoidectomies Total on Label Procedure:	s	461,000 715,000 1,176,000	
"On Label" Market Share †	4.4%	22.7%	56.7%
Total "Potential" Exparel Proce	dures*	42,000,000	
"Off" and "On" Label Market share†	0.1%	0.6%	1.6%
† MLV & CO Estimates	* Pacira Prese	ntation Novembe	r 2014

Exparel has been priced and promoted as if it provides three days of pain relief, even though its label clearly states that the benefit is only 24 hours. This has enabled the product to benefit from premium pricing relative to Ofirmev and what we anticipate for Dex-IN.

We think Exparel's use has been somewhat limited because it must be used during surgery and cannot be readministered following surgery. We believe this along with the higher cost helps to explain the different unit volume and market share figures relative to Ofirmev. Our best estimate suggests "on label" market share of as much 56%, but this is unlikely to be accurate given rampant "off label" use that Pacira readily acknowledges in its corporate presentations (more than 11 other surgical procedures are described as being top procedures that are not on the FDA approved label). Based on the 42 million procedures in which Pacira believes Exparel may be appropriate, it appears that it has just 1.6% market share. In spite of the small rate of overall market penetration, the sales peformance (see paragraph below and graph to left) is impressive.

The tepid launch quickly transformed into one of continiously increasing sales, with total sales reaching \$76 million in 2013. The rapid rise in sales carried the stock on a similar trajectory, the share price started 2013 at \$17 and ended the year just above \$57. The stock has continued to follow sales upward in 2014: with the Exparel currently on a \$200-million run rate the stock now trades near \$90. In less than four years the company has transformed from \$130 million post-IPO valuation prior to commercialization, to a \$3+ billion valuation with Exparel in just its third year on the market.

#### **EXPAREL Commercial Metrics**



Source: Pacira Pharmaceuticals Presentation Nov. 2014

#### **Discussion of Key Model Assumptions**

#### **Launch Supported by Build Out of Commercial Effort**

The first year uptake of Ofirmev and Exparel was slowed by the need to first secure their position on hospital formularies before surgeons would have ready access to use it. Once the formulary positions were secured, use and sales dramatically increased. Our model assumes that Recro retains all commercial rights and responsibilities and must build a sales infrastructure in advance of the product's launch. Pacira was able to successfully launch Exparel with a field sales organization of roughly 60 representative giving them coverage of 80% of their intended targets. We suspect Recro will try to launch with a similarly sized sales organization, but expect it will grow as it funds further studies to demonstrate effectiveness in other types of surgical procedures or settings. The effort to build a commercial infrastructure will require additional capital and create a higher breakeven point than might be the case if Recro outlicensed commercial rights. However, it likely provides for much higher future cash flows than would be the case if it outlicensed.

Importantly, our DCF captures EBITDA but a pharmaceutical company seeking to acquire the company would likely look at contribution margin less capital costs to acquire the company, which would likely result in a much higher valuation than is implied by our DCF.

#### **Licensor as Potential Competitor, Implications for Royalties**

Recro's license for Dex from Orion includes several routes of administration including transmucosal delivery, which covers Recro's planned intranasal and sublingual formulations. Under the license, Recro would owe royalty on net sales ranging from 10%-20% depending on annual sales levels and the status of competition. In the presence of a generic competitor, or a competing product released by Orion or its licensee, the royalty would drop to low single digits. If however, the product from Orion or its licensees involved a competing product in a dosage form covered by the license (transdermal, transmucosal, topical, enteral, or pulmonary) and targeting the treatment of human pain, then it would appear all royalty obligations would cease. Under the license agreement neither Orion, nor its licensees may undertake any development activities for the treatment of human pain using Dex in any of the forms covered by the license until four years after Recro has gained first approval for a product under the license in the U.S. This provision would likely prevent a competitive product from Orion, even in a different route of administration, from entering the pain market in the U.S. for at least 6-7 years after Recro's first approval. We see such a scenario as unlikely at this time.

For modeling purposes we assume 75% gross margins. This includes the impact of 10%-20% royalties, thereby implying pharmaceutical margins for DEX-IN in the more typical range of 85%-95% for specialty pharmaceutical products.

#### **Dilution to Support Development and Commercialization**

Our model assumes all future capital needs for development and commercialization are secured via dilutive equity as opposed to other non-dilutive sources. If management were able to sublicense in territories (e.g. Japan) covered by its license with Orion, then it may be able to reduce the impact of dilution. However, the uncertainty of such options makes it too unlikely to incorporate into our model.

### **APPENDICES**

Recro Pharma (REPH)			2014E					2015E										
Income Statement (\$000)	1QA	2QA	3QA	4QE	Year	1QE	2QE	3QE	4QE	Year	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Dex-IN sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	9,924.0	41,295.9	85,920.2	156,419.9	209,216.1	266,013.7
Cost of goods	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2,481.0	10,324.0	21,480.1	39,105.0	52,304.0	66,503.4
Gross profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7,443.0	30,971.9	64,440.2	117,314.9	156,912.1	199,510.2
R&D expense	227.0	1,837.2	3,633.7	2,500.0	8,197.9	3,000.0	2,000.0	2,000.0	3,500.0	10,500.0	15,000.0	5,000.0	5,000.0	5,000.0	5,000.0	5,000.0	5,000.0	5,000.0
G&A expense	646.6	958.6	1,084.4	1,200.0	3,889.7	1,350.0	1,150.0	1,200.0	1,350.0	<u>5,050.0</u>	5,504.5	6,749.9	24,694.7	27,282.5	35,737.7	54,001.6	78,036.9	88,489.0
Total operating expense	873.6	2,795.8	4,718.1	3,700.0	12,087.5	4,350.0	3,150.0	3,200.0	4,850.0	15,550.0	20,504.5	11,749.9	29,694.7	32,282.5	40,737.7	59,001.6	83,036.9	93,489.0
Operating profit	(873.6)	(2,795.8)	(4,718.1)	(3,700.0)	(12,087.5)	(4,350.0)	(3,150.0)	(3,200.0)	(4,850.0)	(15,550.0)	(20,504.5)	(11,749.9)	(22,251.7)	(1,310.6)	23,702.5	58,313.3	73,875.2	106,021.2
Interest income	0.2	2.3	4.6	3.9	11.0	4.6	3.7	6.0	8.1	22.4	50.0	67.9	176.6	169.1	262.3	714.0	1,558.5	2,721.5
Grant income	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	0.0	0.0	0.0	0.0
Interest expense	(4,272.9)	0.0	0.0	0.0	(4,272.9)	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
Pre-tax profit (loss)	(5, 146.3)	(2,793.5)	(4,713.5)	(3,696.1)	(16,349.4)	(4,345.4)	(3,146.3)	(3,194.0)	(4,841.9)	(15,527.6)	(20,454.5)	(11,682.0)	(22,075.1)	(1,141.5)	23,964.8	59,027.3	75,433.7	108,742.7
Tax (benefit)	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	0.0	0.0	22,420.0	41,322.2
Net income	(5, 146.3)	(2,793.5)	(4,713.5)	(3,696.1)	(16,349.4)	(4,345.4)	(3,146.3)	(3,194.0)	(4,841.9)	(15,527.6)	(20,454.5)	(11,682.0)	(22,075.1)	(1,141.5)	23,964.8	59,027.3	53,013.7	67,420.5
Preferred stock dividends	(1,270.1)	0.0	0.0	0.0	(1,270.1)	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 to common SH	(6,416.4)	(2,793.5)	(4,713.5)	(3,696.1)	(17,619.5)	(4,345.4)	(3,146.3)	(3,194.0)	(4,841.9)	(15,527.6)	(20,454.5)	(11,682.0)	(22,075.1)	(1,141.5)	23,964.8	59,027.3	53,013.7	67,420.5
EPS, diluted	(3.67)	(0.36)	(0.61)	(0.48)	(2.83)	(0.56)	(0.41)	(0.36)	(0.47)	(1.80)	(1.61)	(0.85)	(1.50)	(0.08)	1.62	3.97	3.54	4.48
Weighted average diluted shares	1,749.9	7,707.6	7,707.6	7,707.6	6,218.2	7,707.6	7,707.6	8,957.6	10,207.6	8,645.1	12,707.6	13,707.6	14,707.6	14,707.6	14,757.6	14,857.6	14,957.6	15,057.6
YoY sales growth	-													316.1%	108.1%	82.1%	33.8%	27.1%
Gross margin													75.0%	75.0%	75.0%	75.0%	75.0%	75.0%
Operating margin													nm	nm	27.6%	37.3%	35.3%	39.9%
Tax rate															0.0%	0.0%	29.7%	38.0%
YoY EPS growth																144.7%	-10.8%	26.3%

Source: MLV & Co. estimates

REPH Discounted Cash Flow Analysis	4Q14E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Cash from operations	(3,541.1)	(14,907.6)	(19,704.5)	(10,682.0)	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5	74,142.3	85,075.3	91,463.0	97,687.1	104,189.8	110,812.6	117,539.3	124,841.4
Capital expenditure	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	0.0	0.0	0.0	0.0
Free cash flow (\$000)	(3,541.1)	(14,907.6)	(19,704.5)	(10,682.0)	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5	74,142.3	85,075.3	91,463.0	97,687.1	104,189.8	110,812.6	117,539.3	124,841.4
Time period from now (years)	0.1	1.1	2.1	3.1	4.1	5.1	6.1	7.1	8.1	9.1	10.1	11.1	12.1	13.1	14.1	15.1	16.1	17.1
Annualized hurdle rate	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%
Periodic hurdle rate	1.53%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%	14.0%
Present value of cash flow stream (\$MM)	(3,535)	(12,892)	(14,943)	(7,107)	(10,270)	(4,081)	6,895	18,285	16,289	17,005	19,711	19,842	18,714	17,534	16,400	15,302	14,239	13,267
NPV of free cash flow to the firm 4Q14-2031E	\$140,654																	
Shares at YE 2031	15,858																	
NPV of equity value per share	\$8.87																	

Source: Company reports and MLV & Co. estimates.

Recro Pharma (REPH)			2014E					2015E										
Balance Sheet (\$000)	1QA	2QA	3QA	4QE	Year	1QE	2QE	3QE	4QE	Year	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Cash	29,905.0	27,832.4	23,904.1	20,363.0	20,363.0	16,172.6	13,181.3	34,554.8	29,867.9	29,867.9	10,163.4	44,121.4	26,525.6	18,555.5	33,912.4	80,330.6	127,467.0	183,559.5
Accounts receivable	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1,494.4	6,218.4	12,938.0	23,554.0	31,504.1	40,056.8
Inventory	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1,417.7	5,899.4	12,274.3	22,345.7	29,888.0	38,002.0
Other receivables	35.8	0.0	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8	86.8
Prepaid expense	<u>287.3</u>	270.0	133.7	133.7	<u>133.7</u>	<u>133.7</u>	133.7	<u>133.7</u>	133.7	133.7	<u>133.7</u>	<u>133.7</u>	1,484.7	<u>1,614.1</u>	2,036.9	<u>2,950.1</u>	<u>4,151.8</u>	<u>4,674.5</u>
Current assets	30,228.1	28,102.3	24,124.7	20,583.6	20,583.6	16,393.2	13,401.9	34,775.4	30,088.5	30,088.5	10,384.0	44,342.0	31,009.2	32,374.3	61,248.4	129,267.2	193,097.8	266,379.5
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1,837.5	5,197.5	5, 197.5	5,197.5	5,197.5	5,197.5	5,197.5	5,197.5
Total assets	30,228.1	28,102.3	24,124.7	20,583.6	20,583.6	16,393.2	13,401.9	34,775.4	30,088.5	30,088.5	12,221.5	49,539.5	36,206.7	37,571.8	66,445.9	134,464.7	198,295.3	271,577.0
Accounts payable	32.4	400.2	682.2	682.2	682.2	682.2	682.2	682.2	682.2	682.2	682.2	682.2	2,252.3	2,982.5	4,355.2	6,867.5	9,473.9	11,199.5
Accrued expense	<u>792.4</u>	937.3	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	1,236.2	7,408.4	8,184.7	10,721.3	<u>16,200.5</u>	<u>23,411.1</u>	<u>26,546.7</u>
Current liabilities	824.8	1,337.6	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	9,660.7	11,167.2	15,076.5	23,068.0	32,885.0	37,746.2
Other	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	0.0	0.0	0.0	0.0
Total liabilities	824.8	1,337.6	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	1,918.4	9,660.7	11,167.2	15,076.5	23,068.0	32,885.0	37,746.2
Shareholders' equity	29,403.2	26,764.7	22,206.3	18,665.2	18,665.2	14,474.8	11,483.5	34,694.5	30,007.6	30,007.6	10,303.1	47,621.1	26,546.0	26,404.6	51,369.4	111,396.7	165,410.4	233,830.8
Liabilities & equity	30,228.1	28,102.3	24,124.7	20,583.6	20,583.6	16,393.2	13,401.9	36,612.9	31,926.0	31,926.0	12,221.5	49,539.5	36,206.7	37,571.8	66,445.9	134,464.7	198,295.3	271,577.0

Source: MLV & Co. estimates

Recro Pharma (REPH)			2014E					2015E										
Cash Flow (\$000)	1QA	2QA	3QA	4QE	Year	1QE	2QE	3QE	4QE	Year	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
EBIT	(873.6)	(2,795.8)	(4,718.1)	(3,700.0)	(12,087.5)	(4,350.0)	(3,150.0)	(3,200.0)	(4,850.0)	(15,550.0)	(20,504.5)	(11,749.9)	(22,251.7)	(1,310.6)	23,702.5	58,313.3	73,875.2	106,021.2
D&A	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	0.0	0.0	0.0	0.0
Stock compensation expense	<u>19.5</u>	<u>155.0</u>	<u>155.0</u>	<u>155.0</u>	<u>484.5</u>	<u>155.0</u>	<u>155.0</u>	<u>155.0</u>	<u>155.0</u>	620.0	<u>750.0</u>	<u>1,000.0</u>	<u>1,000.0</u>	<u>1,000.0</u>	1,000.0	<u>1,000.0</u>	1,000.0	<u>1,000.0</u>
EBITDA	(854.2)	(2,640.8)	(4,563.1)	(3,545.0)	(11,603.0)	(4,195.0)	(2,995.0)	(3,045.0)	(4,695.0)	(14,930.0)	(19,754.5)	(10,749.9)	(21,251.7)	(310.6)	24,702.5	59,313.3	74,875.2	107,021.2
Cash interest income (expense)	0.2	2.3	4.6	3.9	11.0	4.6	3.7	6.0	8.1	22.4	50.0	67.9	176.6	169.1	262.3	714.0	1,558.5	2,721.5
Cash tax	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	0.0	0.0	(22,420.0)	(41,322.2)
Accounts receivable	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(1,494.4)	(4,724.0)	(6,719.6)	(10,616.0)	(7,950.1)	(8,552.7)
Inventory	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(1,417.7)	(4,481.7)	(6,374.9)	(10,071.4)	(7,542.3)	(8,113.9)
Prepaid expense	(271.6)	17.3	136.3	0.0	(118.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(1,351.0)	(129.4)	(422.8)	(913.2)	(1,201.8)	(522.6)
Other receivables	2.6	35.8	(86.8)	0.0	(48.4)	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
A/P & accrued expense	306.9	681.6	580.8	0.0	1,569.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7,742.3	1,506.5	3,909.3	7,991.4	9,817.0	4,861.2
Other	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	0.0	0.0	0.0	0.0
Cash from operations	(815.9)	(1,903.8)	(3,928.2)	(3,541.1)	(10,189.1)	(4,190.4)	(2,991.3)	(3,039.0)	(4,686.9)	(14,907.6)	(19,704.5)	(10,682.0)	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5
Capital expenditures	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	0.0	0.0	0.0	0.0
Free cash flow	(815.9)	(1,903.8)	(3,928.2)	(3,541.1)	(10,189.1)	(4,190.4)	(2,991.3)	(3,039.0)	(4,686.9)	(14,907.6)	(19,704.5)	(10,682.0)	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5
Cash from operations	(815.9)	(1,903.8)	(3,928.2)	(3,541.1)	(10,189.1)	(4,190.4)	(2,991.3)	(3,039.0)	(4,686.9)	(14,907.6)	(19,704.5)	(10,682.0)	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5
Cash from investing	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	0.0	0.0	0.0	0.0
Cash from financing	30,708.1	(168.8)	0.0	0.0	30,539.3	0.0	0.0	24,412.5	0.0	24,412.5	0.0	44,640.0	0.0	0.0	0.0	0.0	0.0	0.0
Net change in cash	29,892.2	(2,072.6)	(3,928.2)	(3,541.1)	20,350.2	(4,190.4)	(2,991.3)	21,373.5	(4,686.9)	9,504.9	(19,704.5)	33,958.0	(17,595.8)	(7,970.1)	15,356.9	46,418.2	47,136.4	56,092.5
Cash, beginning	12.8	29,905.0	27,832.4	23,904.1	12.8	20,363.0	16,172.6	13,181.3	34,554.8	20,363.0	29,867.9	10,163.4	44,121.4	26,525.6	18,555.5	33,912.4	80,330.6	127,467.0
Cash, ending	29,905.0	27,832.4	23,904.1	20,363.0	20,363.0	16,172.6	13,181.3	34,554.8	29,867.9	29,867.9	10,163.4	44,121.4	26,525.6	18,555.5	33,912.4	80,330.6	127,467.0	183,559.5
Cash, average	14,958.9	28,868.7	25,868.2	22,133.6	10,187.9	18,267.8	14,677.0	23,868.1	32,211.4	25,115.5	20,015.7	27,142.4	35,323.5	22,540.5	26,233.9	57,121.5	103,898.8	155,513.2
Interest income rate	0.01%	0.03%	0.07%	0.07%	0.11%	0.10%	0.10%	0.10%	0.10%	0.09%	0.25%	0.25%	0.50%	0.75%	1.00%	1.25%	1.50%	1.75%
Interest income	0.2	2.3	4.6	3.9	11.0	4.6	3.7	6.0	8.1	22.3	50.0	67.9	176.6	169.1	262.3	714.0	1,558.5	2,721.5
Courses MIV Co. antimotes													•		•			

Source: MLV & Co. estimates

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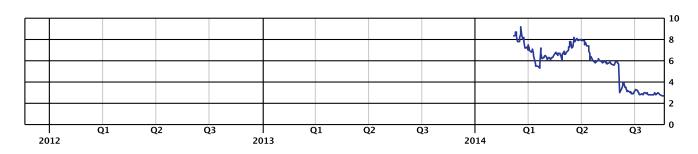
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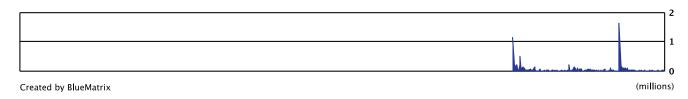
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#### Recro Pharma, Inc. (REPH): Share Price (in USD) and Volume History as of 11-21-2014





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	COMPANIES UI	NDER COVERAGE	INVESTMENT BANKING SERVICE WITHIN 12 MON							
Rating	Count	Percent	Count	Percent						
BUY	107	64.85%	50	30.30%						
HOLD	58	35.15%	21	12.73%						
SELL	0	0.00%	0	0.00%						

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