

Recro Pharma, Inc.

(REPH/ NASDAQ)

March 19, 2014

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Derisked Pain Drug Addressing Large Market Opportunities – Initiating At Buy

Buy
PT: \$26.00

Investment Summary

We are initiating coverage of Recro Pharma, Inc. with a Buy rating and \$26 target price. We view lead drug Dex-IN, an intranasal alpha-2 agonist for post-operative pain, to be substantially derisked in three important ways. We view safety as derisked by 15 years of use of Precedex, a continuous IV infusion of dex approved as a sedative in the ICU at 10 times the dose delivered by Dex-IN, but which importantly cannot compete with Dex-IN in any of its potential indications. We view efficacy as derisked by earlier positive Phase 2 results in chronic lower back pain to be followed next by a bunionectomy trial that should involve sufficiently more pain, and thus a lower placebo response. Finally, we view commercialization as derisked by our financial model supporting a substantially higher valuation than at present when it only incorporates U.S. sales in the post-operative setting in less than 1% of that market. We therefore see considerable room for upside from a stronger uptake in the post-operative setting and/or Dex-IN usage in other indications, particularly cancer breakthrough pain, not to mention any success with Dex-SL, the sublingual formulation. Orion has Precedex rights in several ex-U.S. territories including the E.U., and another attractive feature of Recro is that should Orion wish to commercialize Dex-IN or Dex-SL in those regions, it would owe Recro almost half of Recro's R&D investment in that formulation. We also believe that management has proven itself before with its clinical, regulatory, and commercial successes.

Discussion

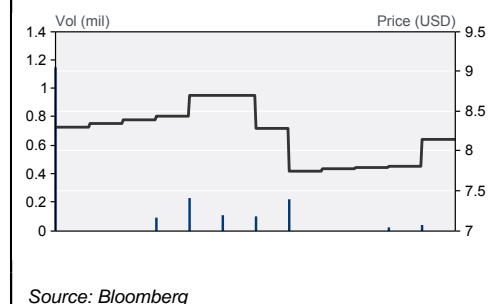
- **We are initiating coverage of Recro Pharma, Inc. with a Buy rating and a 12-month target price of \$26.** Recro is focused on developing drugs for the management of various types of pain. Its lead drug, Dex-IN, is the intranasal formulation of dexmedetomidine (dex) initially being developed for post-operative pain relief. As an alpha-2 agonist, dex is free of opioid-associated side effects such as being addictive, causing respiratory depression, GI complications, and cognitive confusion. In addition, IV dex under the brand name of Precedex has been used in the ICU for sedation since 1999 at 10 fold the dose delivered by Dex-IN, and Precedex's clean track record speaks to safety. We emphasize that as a continuous IV approved only for inpatient sedation, Precedex is not a competitive threat to the markets targeted by Recro with Dex-IN. A family of patents for Dex-IN has been filed, and if issued, should protect Dex-IN through 2030.
- **We anticipate several near- and intermediate-term catalysts for Dex-IN in post-operative pain.** Dex-IN will enter Phase 2b in 150-200 patients following bunionectomy surgery, with top-line results expected late in 2014, a highly anticipated event that would be a key value creation catalyst for Recro. Following a successful Phase 2b, Dex-IN will be evaluated in two Phase 3 trials, intra-abdominal surgery and an orthopedic surgery, with completion of both trials expected in 2H15. Recro intends to submit a 505(b) (2) NDA shortly thereafter, with FDA approval expected one year from filing. With its recent IPO, Recro is well-funded to conduct the planned Phase 2b and Phase 3 trials, and Recro's licensor Orion would reimburse almost half of Recro's R&D spend, if Orion wishes to commercialize Dex-IN in its territories, a feature that we find very attractive to the company.
- **The U.S. market for post-operative pain is large, with about 40 million procedures requiring a post-operative pain medication generating U.S. sales of \$5.9 billion in 2010.** Dex-IN is the only alpha-2 agonist being developed for post-operative pain. Even with our highly conservative modeling of a very low penetration rate, we are able to support a far higher valuation than the current level. Our valuation only takes into consideration the post-operative setting, thus should Recro pursue cancer breakthrough pain, sales from that setting would likely be in the same range as for the post-operative setting, representing considerable upside to our revenue forecast.

Valuation / Target Price

We derive our target price of \$26 through a DCF analysis, assuming a 25% discount rate that is applied to all cash flows and the terminal value, which is based on a 5 multiple of the projected 2020 EBITDA of \$101 million.

Price	\$8.15
52-Week High/Low	\$8.95-\$7.50
Shares Out (mm)	7.7
Market Cap (mm)	\$63
Avg. Daily Vol (000)	NA
EV (mm)	NA

EPS	FY13A	FY14E	FY15E
Mar	--	\$(0.36)	--
June	--	\$(0.26)	--
Sept	--	\$(0.45)	--
Dec	--	\$(0.56)	--
FY (Dec)	\$(15.41)	\$(1.66)	\$(1.76)
P/E (x)	NM	NM	NM
Revenue (\$M)			
Mar	--	\$0.0	--
June	--	\$0.0	--
Sept	--	\$0.0	--
Dec	--	\$0.0	--
FY (Dec)	\$0.0	\$0.0	\$0.0



Investment Thesis

We are initiating coverage of Recro Pharma, Inc. with a Buy rating and a 12-month target price of \$26. Recro is focused on developing drugs for the management of various types of pain. Its lead drug, Dex-IN, is the intranasal formulation of dexmedetomidine (dex) being developed for post-operative pain relief. As an alpha-2 agonist, dex is free of opioid-associated side effects such as being addictive, causing respiratory depression, GI complications, and cognitive confusion. We believe hospitals will highly appreciate the non-opioid nature of Dex-IN as fewer complications mean lower surgery costs and better patient satisfaction. In addition, IV dex under the brand name of Precedex has been used in U.S. hospital intensive care units for sedation since 1999, where the dose of dex is about 10 fold of that contained in Dex-IN. Precedex's clean track record gives us confidence in the safety of Dex-IN and thus substantially derisks the Dex-IN program, in our view. We emphasize that as a continuous IV approved only for inpatient sedation, Precedex is not a competitive threat to the outpatient post-operative market targeted by Recro with Dex-IN. Dex-IN's convenient intranasal formulation allows it to be administered in an outpatient setting, such that patients receive the first dose of dex following surgery at the hospital, and self-administer subsequent doses for 5 to 7 days at home at an estimated frequency of about every 4-6 hours. A family of patents for Dex-IN has been filed, and if issued, should protect Dex-IN through 2030.

We anticipate several near-term catalysts for Dex-IN in the post-operative pain relief setting. Dex-IN will enter Phase 2b in 150-200 patients following bunionectomy surgery, with top-line results expected late in 2014, a highly anticipated event that would be a key value creation catalyst for Recro. Following the successful completion of the Phase 2b trial, Dex-IN will be evaluated in two Phase 3 trials, one in patients undergoing intra-abdominal surgery and the other in patients undergoing an orthopedic surgery, with completion of both trials expected in 2H15. Recro intends to submit a 505(b)(2) NDA shortly thereafter, with FDA approval expected one year from filing. With its recent IPO, Recro is well-funded to conduct the planned Phase 2b and Phase 3 trials, and Recro's licensor Orion would reimburse almost half of Recro's R&D spend, if Orion wishes to commercialize Dex-IN in its territories, a feature that we find very attractive to the story.

Previously, Dex-IN was evaluated in a Phase 1b trial in 24 chronic lower back pain patients, where it exhibited a statistically significant improvement in summed pain intensity difference (SPID) versus placebo as early as well within one hour post-dosing. Dex-IN's Phase 2b bunionectomy trial should show even more of a treatment effect than what was observed in chronic lower back pain given the greater intensity of pain and thus the expected poor placebo response. Thus, we believe that conducting the next trial in bunionectomy derisks efficacy, which when combined with the safety seen with 10 fold higher doses of dex given IV, substantially derisks the entire trial. We note that the Phase 2b trial is the lone significant investment catalyst for 2014, and that this arguably low level of risk is far more the exception than the rule in drug development.

The market for post-operative pain relief is large. About 40 million procedures requiring a post-operative pain medication such as Dex-IN are performed each year in the U.S., and U.S. sales of post-operative pain drugs reached \$5.9 billion in 2010. To our knowledge Dex-IN is the only alpha-2 agonist that is being developed for post-operative pain relief.

Even with our highly conservative modeling of a very low penetration rate, we are able to support a far higher valuation than the current. Our valuation only takes into consideration the post-operative setting; thus should Recro pursue the next potential Dex-IN indication of cancer breakthrough pain relief, sales from that setting would likely be in the same range as for the post-operative setting, representing considerable upside to our revenue forecast.

Lastly, we believe Recro has a strong management team that has significant experience conducting clinical development and commercialization, and who will replicate that success with Dex-IN. Gerri Henwood has served as Recro's CEO since the company's inception in 2008. She had extensive experience running publicly-traded and privately-held biopharmaceutical companies, and was actively involved in clinical and commercial development. From 1999 to 2006, Ms. Henwood was the co-founder and CEO of Auxilium Pharmaceuticals (AUXL, Sell) where she swiftly developed and commercialized Testim. From 1985 to 1999, Ms. Henwood was the founder and CEO of IBAH, a public contract research organization reaching a net revenue level of \$150 million before being acquired by Omnicare in 1998. IBAH conducted about 800 clinical trials for its clients, leading to about 60 filed NDAs, all of which received approval.

Exhibit 1: Product pipeline

Product	PC	I	II	III	Rights
Dexmedetomidine ("Dex")					WW, exc. Europe, Turkey, CIS*
Dex- IN (intranasal)					
Post-operative pain					
Cancer breakthrough pain					
Dex-SL (sublingual)					
Transdermal					
Fadolmidine ("Fado")					WW, exc. Europe, Turkey, CIS*
Intrathecal					
Post-operative pain					
Topical					
Neuropathic pain					

* CIS currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.

Source: Company documents

Exhibit 2: Catalyst calendar

Event	Anticipated Completion Timing
Post-Operative Pain Study (6 month Phase IIb study in 150-180 pts)	2H '14
Post-Op Pain – Intra-Abdominal Surgery (pivotal Phase III study; 6-9 months in 200+ pts)	2H '15
Post-Op Pain – Orthopedic Surgery (pivotal Phase III study; 6-9 months in 200+ pts)	2H '15
NDA filing	Shortly after Ph III
NDA Approval	12 months review period

Source: Company documents

Valuation

We derive our target price of \$26 through a DCF analysis, assuming a 25% discount rate that is applied to all cash flows and the terminal value, which is based on a 5 multiple of the projected 2020 EBITDA of \$101 million. All projected revenue is due to Dex-IN sales in the U.S. for post-operative pain relief. Our revenue build assumes an addressable market of 40 million surgeries requiring post-operative pain management in the U.S., and a cost per regimen of about \$800 in the U.S, in line with the treatment cost of a branded oral opioid. We are conservatively modeling our market penetration for Dex-IN, although we believe that demand for Dex-IN would be large given that Dex-IN, if approved, would be a non-opioid analgesic with a convenient intranasal route of delivery, and yet we are still able to arrive at a valuation that is substantially higher than the current level. Our valuation assumes a U.S. launch in 2Q17, given Recro's plan of initiating a Phase 2b trial of Dex-IN with results in 2H14 and completing Phase 3 trials of Dex-IN in 2H16. For modeling purposes, our valuation does not include any collaborative revenues, which are potential sources of non-dilutive funding that could amount to more than the company's current market value. We also believe we are being conservative by not yet factoring in the pipeline value behind Dex-IN for post-operative pain relief. Sales from the next potential Dex-IN indication, cancer breakthrough pain relief, would represent upside to our revenue forecast and we estimate that those sales would likely be in the same range as for the post-operative setting.

Management

Gerri Henwood has served as Recro's CEO and a director since the company's inception in 2008. Ms. Henwood is also a director at Alkermes, a global biopharmaceutical company, and two private companies. She had extensive experience of running publicly-traded and privately-held biopharmaceutical companies, and was actively involved in clinical and product development. Ms. Henwood has served as the President of consulting firm MCG from 2006 to 2013, and she continues to spend limited time providing consulting services to other companies, including other drug companies. From 1999 to 2006, Ms. Henwood was the co-founder and CEO of Auxilium Pharmaceuticals. From 1985 to 1999, Ms. Henwood was the founder and CEO of IBAH, a NASDAQ traded contract research company reaching a net revenue level of \$150 million before being acquired by Omnicare in 1998. Prior to her involvement with IBAH, Ms. Henwood was at what is now GlaxoSmithKline (brand manager, head of U.S. Regulatory and Medical Affairs, Group Director – Marketing in the International Pharmaceutical Division). Ms. Henwood holds a B.S. in Biology from Neumann University.

Dex-IN and Dex-SL

History of Dex-IN and Dex-SL

Dexmedetomidine (or dex) is approved as an injectable alpha-2 adrenergic agonist that is commercialized by Hospira in the U.S. under the brand name Precedex and by Orion in Europe under the brand name Dexdor for sedation in hospital intensive-care units. Precedex went generic in the U.S. in January 2014, and at present four companies have filed to sell a generic equivalent of Precedex in the U.S. Although no ANDAs have yet been

approved, we believe that generic competition is coming in 2014. We emphasize that Precedex and any generic equivalents are continuous IV infusions that, owing to a large difference in half-life (60-90 minutes IV vs. 2.17 hours as an IN at 50µg vs. 3.25 hours as a SL), would in no way be a competitive threat to an every 4-6 hour IN administration of 100 microliters of Dex-IN in the post-operative setting, especially after leaving the hospital. Recro in-licensed worldwide (except Europe, Turkey, and the Commonwealth of Independent States, or CIS) rights of non-injectable formulations of dex from Orion, and will develop intranasal dex (or Dex-IN) for post-operative pain relief in an outpatient setting, such that patients receive the first dose of dex following surgery at the hospital, and self-administer subsequent doses for 5 to 7 days at home at an estimated frequency of about every 4-6 hours. A convenient combination of benefits from dex is its anxiolytic and analgesic qualities. As part of the transaction with Orion, Recro is entitled to have almost half of its total R&D spend on a given dex formulation reimbursed sometime after Phase 3 is complete, if and only if Orion wishes to commercialize that formulation in its territories, a feature that we find very attractive to the story. Orion just received approval in many of its territories so there is 10 years of exclusivity from which to benefit with any effective formulation of dex. Recro is pursuing a section 505(b)(2) regulatory strategy for Dex-IN, which allows the company to cross-reference the existing safety data from the NDA and MAA of Precedex and Dexdor. We note that physicians are already familiar with dex (100,000s of patients worth of commercial experience), which we believe will drive adoption if proven successful in the clinic, and that dex given IV is about a 10x dose of what will be given IN, so safety is unlikely to be an issue. Following potential FDA approval of Dex-IN for post-operative pain, Recro may elect to pursue additional approvals of Dex-IN for cancer breakthrough pain as well as approvals for sublingual dex (or Dex-SL) in instances where the slower onset of action from sublingual administration is sufficient. There is no other alpha-2 agonist compound in development for post-operative pain relief.

Alpha 2 agonists are non-narcotic and non-scheduled agents that stimulate alpha 2 adrenaline receptors in the central nervous system and the peripheral nervous system. As a result, they inhibit the release of neurotransmitters and impede transmission of sympathetic nerve impulses, providing the dual effect of sedation and analgesia. Even at high doses, the alpha 2 agonists elicit analgesic, sedative, and anxiolytic effects without impairing the respiratory function. Bradycardia, hypotension, and dry mouth are the most common side effects of alpha 2 agonists.

Alpha 2 agonists have been in clinical use for a long time, with clonidine initially approved for hypertension (Catapres) in 1974 and then for pain (Duraclon) in 1996, and dex approved for sedation (Precedex) in 1999. Duraclon, delivered via a continuous epidural infusion device, is indicated in combination with opioids for the treatment of severe pain in cancer patients that is not adequately relieved by opioids alone. Compared to clonidine, dex is highly selective with an alpha-2 to alpha-1 ratio of 1600:1, or approximately eight times that of clonidine, which may enable dex to have enhanced analgesic effects compared to clonidine, and dex also causes less of a drop in blood pressure. Moreover, the intranasal formulation of Dex-IN is more patient friendly than the epidural formulation of Duraclon, thus we expect wider use of Dex-IN upon approval.

Exhibit 3: Major alpha 2 agonists

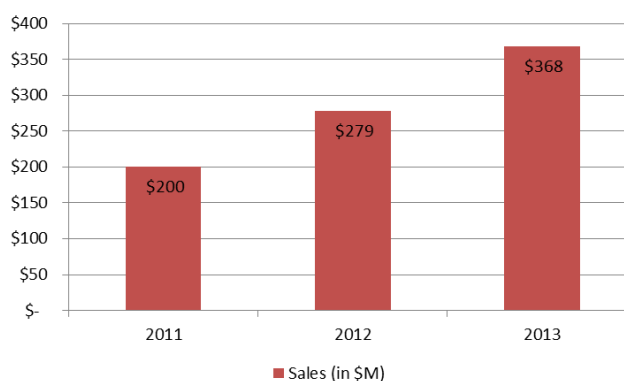
Company	Drug	Indication	Approval Date	Delivery
Mylan	Duraclon (clonidine)	in combination with opiates for the treatment of severe pain in cancer patients that is not adequately relieved by opioid analgesics alone	Oct-96	epidural injection
Boehringer Ingelheim	Catapres (clonidine)	hypertension	Sep-74	oral tablets
Hospira	Precedex (dex)	sedation	Dec-99	infusion

Source: Brean Capital research

Exhibit 4: Major differences in the pharmacology of clonidine and dexmedetomidine

Clonidine	Dexmedetomidine*
Developed in the 1960s	Developed in the 1980s
Clinical practice: originally prescribed as an antihypertensive then as an analgesic in chronic pain (1983)	Clinical practice: tested in volunteers (1991) then used as a sedative in ICU (1999)
Ratio $\alpha_2:\alpha_1$ receptor binding is 200:1	Ratio $\alpha_2:\alpha_1$ receptor binding is 1600:1
Octanol/buffer partition coefficient: 0.8	Octanol/buffer partition coefficient: 2.8 More lipophilic (3.5-fold) than clonidine
Plasmatic half-life $T_{1/2}$: 9-12 hours	Plasmatic half-life $T_{1/2}$: 2-2.5 hours
Protein binding: 50%	Protein binding: 94%
*Detomidine, the racemic mixture, is widely used in veterinary medicine; dexmedetomidine is the active isomer of medetomidine. ICU, intensive care unit.	

Source: Grosu I, Lavand'homme P. Use of dexmedetomidine for pain control. F1000 Medicine Reports 2010, 2:90

Exhibit 5: Precedex had significant growth in use in the U.S.

Source: Company documents and Brean Capital research

Clinical Trials

Recro completed eight trials, including two placebo-controlled Phase 1b trials for chronic lower back pain, in more than 100 patients to evaluate various formulations of dex for moderate to severe pain. Despite Dex-IN's efficacy in chronic pain, Recro decided to move forward with the post-operative pain (5-7 days following surgery) indication as it would be much more costly and time consuming to develop Dex-IN for the chronic pain indication. The FDA is likely to require carcinogenicity studies and chronic pain studies before granting a chronic pain indication, versus modest GLP toxicology studies and short-term duration studies for a post-operative pain indication. As such, Recro intends to initiate a Phase 2b trial of Dex-IN for post-operative pain in bunionectomy in time to have results by YE14. While the initial commercial use of Dex-IN would be limited to post-operative pain, Recro plans to expand into cancer breakthrough pain and chronic pain. The company would also pursue the development of Dex-SL following Dex-IN's potential approval.

Planned Post-Operative Pain Trials of Dex-IN

Recro plans to initiate a randomized placebo-controlled Phase 2b trial of Dex-IN in 150-200 post-surgical patients following bunionectomy surgery. The Phase 2b trial will assess the efficacy of Dex-IN to control moderate-to-severe post-operative pain over 48 to 72 hours compared to a placebo, with the primary endpoint being summed pain intensity difference (SPID) scores over 48 hours after surgery, with LOCF used for any missing data. Dex-IN will be taken by patients every 4-6 hours as per patient need for at least 48 hours. The trial will also assess the tolerability and safety of Dex-IN, including blood pressure and sedation observations. We note that all future trials will depend solely on patient reported AEs and not on solicitation of them, and we have already seen the more favorable safety profile in the absence of solicitation. The trial should last 6 months with top-line results expected in 2H14. Following the completion of the Phase 2b trial, Recro plans to conduct two Phase 3 trials with Dex-IN in post-operative pain, one in patients undergoing intra-abdominal surgery and the other in patients undergoing orthopedic surgery. Each of these Phase 3 trials should take 6-9 months to complete and enroll more than 200 patients, with completion expected in 2H15. In addition, Recro will conduct preclinical animal toxicology studies and human safety clinical trials as per FDA request. Based on efficacy and safety results from Phase 3 trials and other trials, Recro intends to submit a 505(b)(2) NDA shortly thereafter, with FDA approval expected one year from filing.

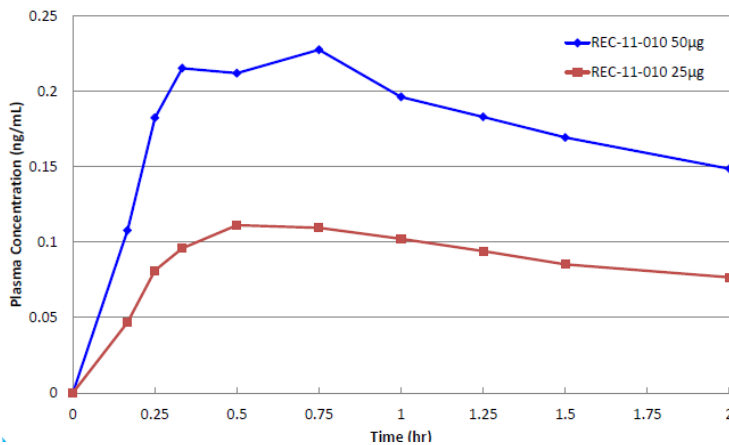
REC-11-010 Chronic Pain Trial of Single-Dose Dex-IN

REC-11-010 was a placebo-controlled three-period cross-over Phase 1b trial of Dex-IN in 24 chronic lower back pain (CLBP) patients, with or without prior use of chronic opioid therapy (about half washed out after opioids and half after NSAIDs). Patients received a single dose of placebo, Dex-IN 25µg, or Dex-IN 50µg, and were allowed to cross over to any arm. The efficacy endpoints were pain intensity, measured at various times up to 6 hours post-dosing, and pain relief, measured at various times up to 60 minutes post-dosing. Pain was triggered by making patients climb stairs until they felt pain, immediately after which they would receive drug or placebo.

Efficacy. Both doses of Dex-IN had a fast onset of analgesic action that lasted several

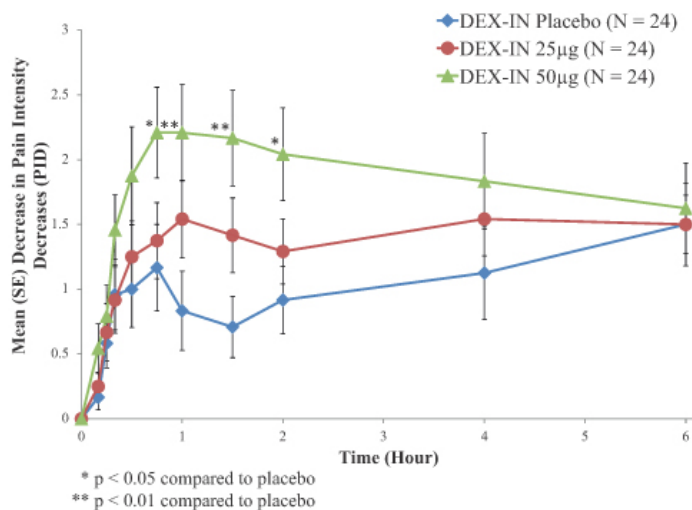
hours. Regarding the measurement of mean pain intensity difference (PID) from baseline, the 25µg and 50µg doses both resulted in a rapid onset of analgesia within 30 minutes of administration and sustained the analgesia for up to four hours, while the 50µg dose showed statistically significant ($p < 0.05$) improvement at the 45, 60, 90 minute time points as well as the 2 hour time point. The 50µg dose also resulted in a statistically significant improvement in summed pain intensity difference (SPID; FDA's preferred primary endpoint for pain) over the initial one-hour period, which was the primary efficacy endpoint in this trial. Regarding the measurement of pain relief, the 50µg dose resulted in statistically significant relief starting at 30 minutes post-dosing through 60 minutes post-dosing.

Exhibit 6: REC-11-010 – mean dexmedetomidine plasma concentration (ng/mL)

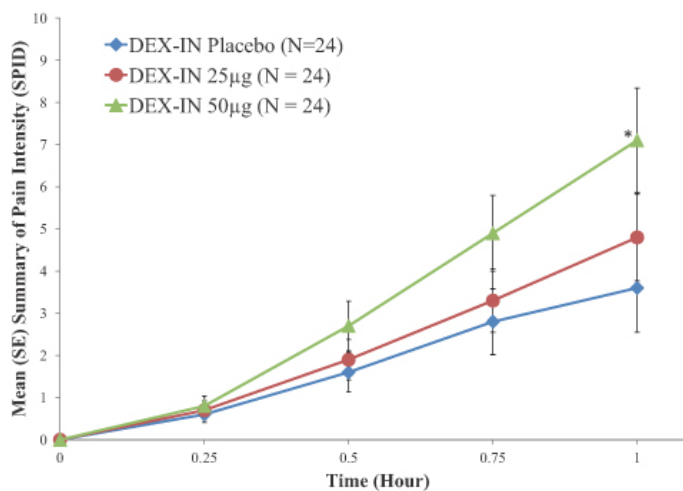


Source: Company documents

Exhibit 7: REC-11-010 – pain intensity difference (PID)

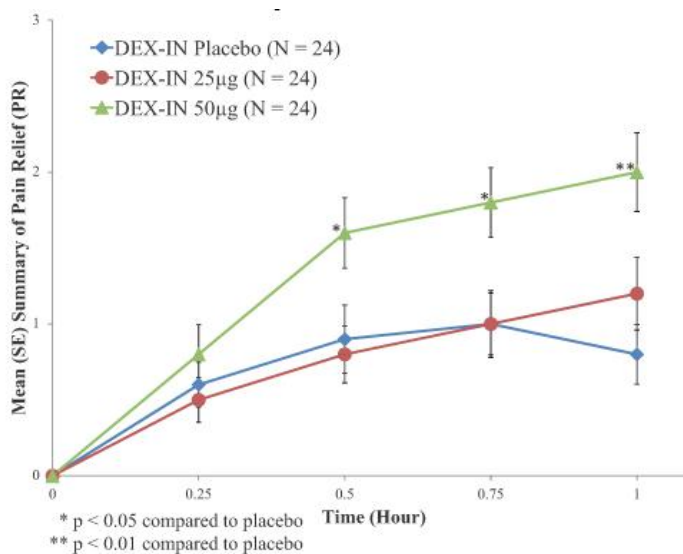


Source: Company documents

Exhibit 8: REC-11-010 - summed pain intensity differences (SPID)

* p < 0.05 compared to placebo

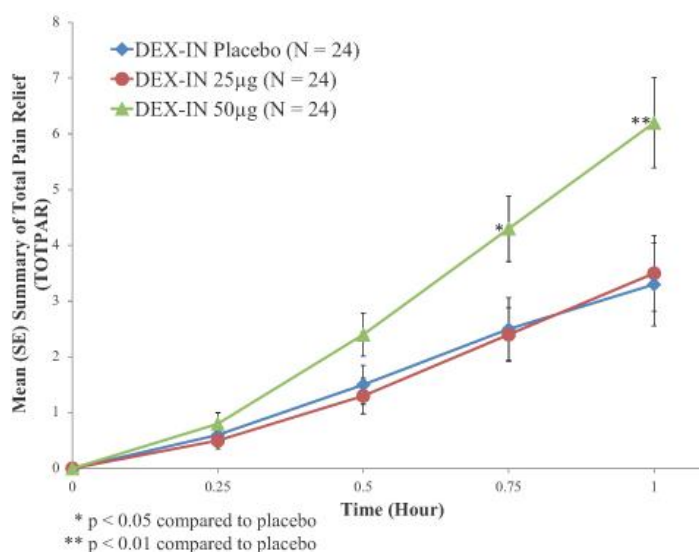
Source: Company documents

Exhibit 9: REC-11-010 - pain relief (PR)

* p < 0.05 compared to placebo

** p < 0.01 compared to placebo

Source: Company documents

Exhibit 10: REC-11-010 - total pain relief (TOTPAR)

Source: Company documents

Safety. Dex-IN was well tolerated. Patients were asked every 15 minutes if they were feeling any AE, which by the power of suggestion tends to inflate the frequency of AEs. AEs were generally mild and did not cause any patients to discontinue Dex-IN. The most common AEs were somnolence, dizziness, nausea, headache, and hypotension. Cases of mild sedation were reported within 60 minutes after dosing, and were more frequent in the 50µg dose arm. Mean nasal irritation scores were below one on a scale of zero (no symptoms) to ten (worse possible symptoms), and AEs related to nasal discomfort were infrequent. In terms of vital signs, Dex-IN decreased blood pressure and heart rate by a greater amount than did placebo, with the 50µg dose having a greater effect than the 25µg dose. As such, there were more reports of asymptomatic hypotension and bradycardia with the 50µg dose.

Exhibit 11: REC-11-010 - adverse events reported by more than one subject

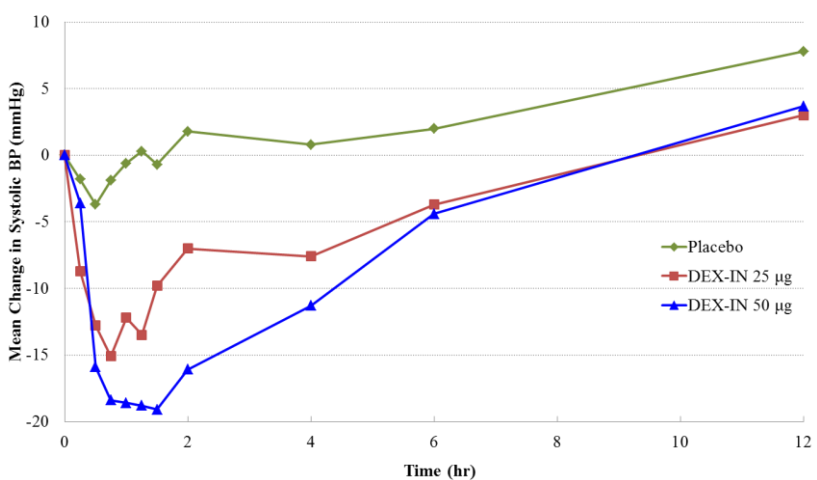
	Placebo (n=24)	DEX-IN 25 µg (n=24)	DEX-IN 50 µg (n=24)
Dry Mouth	-	2	2
Nausea	1	3	5
Vomiting	-	1	2
Feeling Abnormal	-	2	3
BP Decrease	-	-	2
Dizziness	4	5	10
Headache	1	4	4
Paraesthesia	-	-	2
Sinus Headache	-	2	1
Somnolence	-	6	18
Nasal Congestion	-	-	2
Nasal Discomfort	-	1	3
Hypotension	-	4	7

Source: Company documents

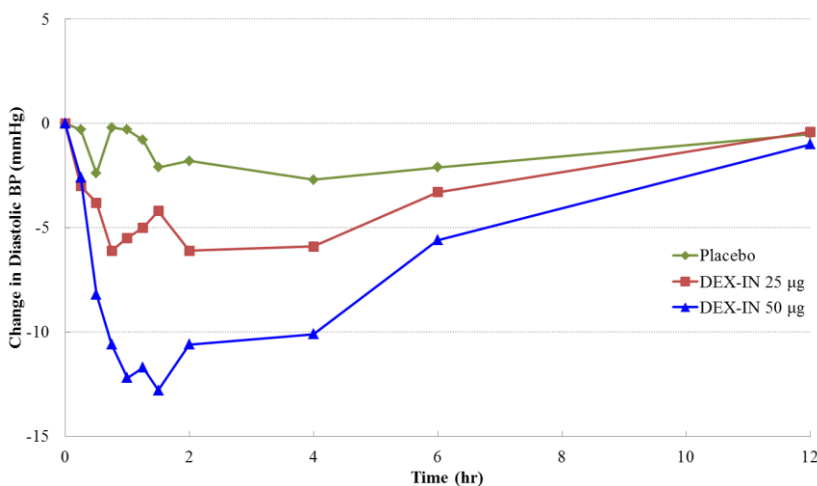
Exhibit 12: REC-11-010 - vital sign assessment

<u>Term</u>	<u>Number of Subject Meeting Criteria</u>		
	<u>Placebo</u> <i>n</i> = 24	<u>DEX-IN 25µg</u> <i>n</i> = 24	<u>DEX-IN 50µg</u> <i>n</i> = 24
Hypotension	2	8	10
Bradycardia	-	-	2
Ortho. Hypotension	1	2	2

Source: Company documents

Exhibit 13: REC-11-010 - resting systolic blood pressure (baseline≈118 mmHg)

Source: Company documents

Exhibit 14: REC-11-010 - resting diastolic blood pressure (baseline≈68 mmHg)

Source: Company documents

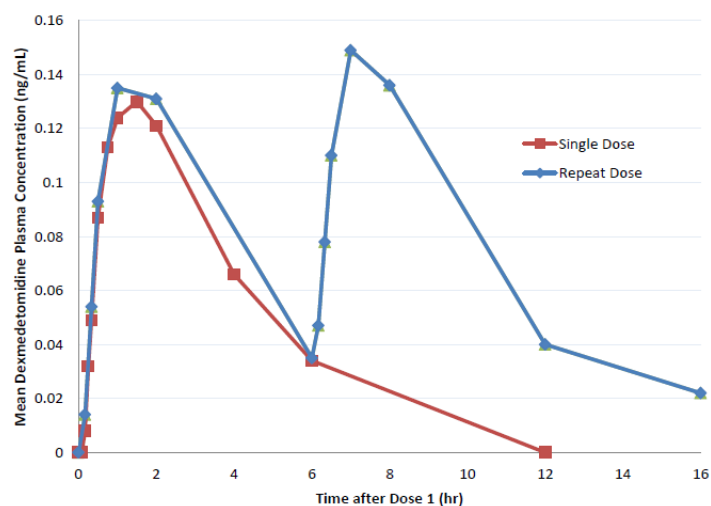
REC-09-003 Chronic Pain Trial of Dex-SL

REC-09-003 was a placebo-controlled Phase 1b trial of Dex-SL in 21 chronic lower back pain (CLBP) patients. The trial consisted of a single-dose cross-over phase, where patients were randomized to receive placebo or Dex-SL 50µg, as well as an open-label repeat-dose phase following a 5 day washout from the cross-over phase, where patients received two doses of Dex-SL 50µg separated by six hours. The efficacy endpoints were pain intensity and pain relief. Pain intensity was measured by a 100mm Visual Analog Scale of Pain (VASpain) at various times up to 6 hours post-dosing, while pain relief was measured by a 5-point pain relief scale (0=no relief, 4=complete relief) at various times up to 60 minutes post-dosing. Dex-SL was shown to reduce pain intensity and provide pain relief with good tolerability.

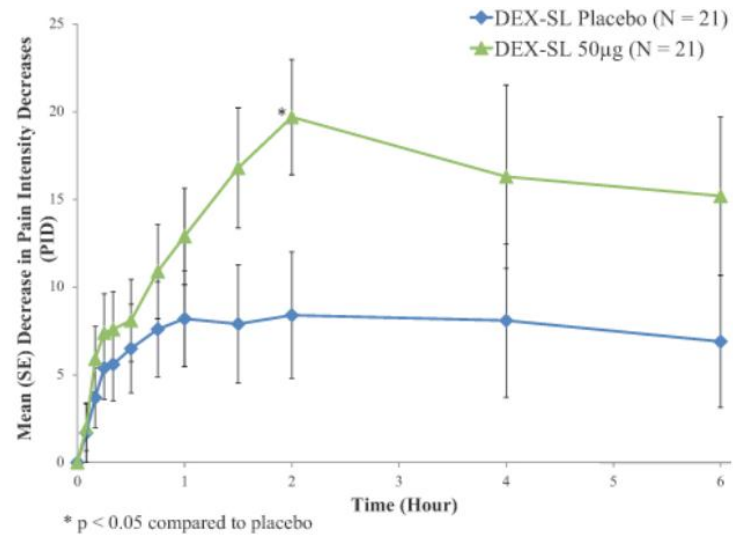
Efficacy. A single 50µg dose of Dex-SL yielded a C_{max} of 0.14ng/mL, a T_{max} of 1.52hrs, and an elimination half-life of 2.17 hours. Regarding the measurement of mean pain intensity difference (PID) from baseline, the 50µg dose of Dex-SL resulted in numerically superior PID scores relative to placebo, and the improvement was statistically significant (p<0.05) at the 2 hour time point. Regarding the measurement of pain relief, the Dex-SL 50µg dose resulted in statistically significant pain relief at the 60 minute time point.

Safety. Dex-SL was well tolerated. AEs were typically mild in severity and did not lead to any discontinuations during the trial. Only two SAEs were reported, one was migraine in the cross-over phase and the other was dizziness in the repeated dose phase. In the single-dose cross-over phase, the most common AEs were dizziness, nasal congestion, and hypotension. In the repeated dosing phase, the most common AEs were orthostatic or postural hypotension, headache, and dizziness, and sedation was more frequent with Dex-SL than placebo. In terms of vital signs, Dex-SL reduced blood pressure compared to placebo but the reductions were transient and were not associated with AEs. Dex-SL did not change heart rate compared to placebo.

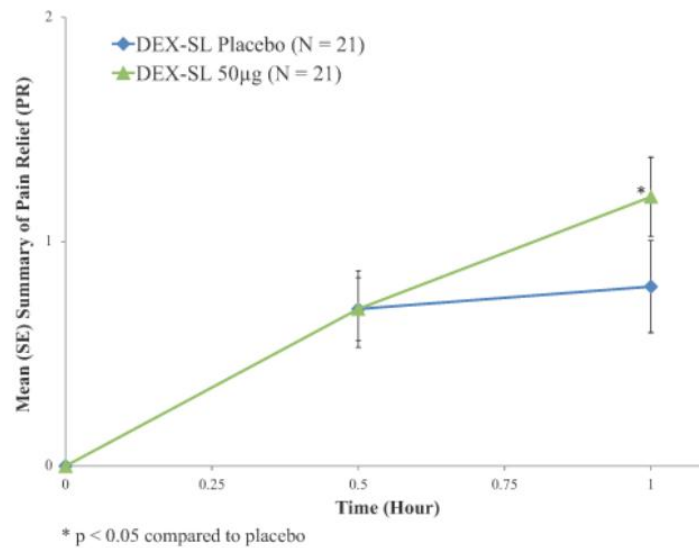
Exhibit 15: REC-09-003 - mean dex plasma concentration on single and repeat dosing of Dex-SL



Source: Company documents

Exhibit 16: REC-09-003 – pain intensity difference

Source: Company documents

Exhibit 17: REC-09-003 – pain relief

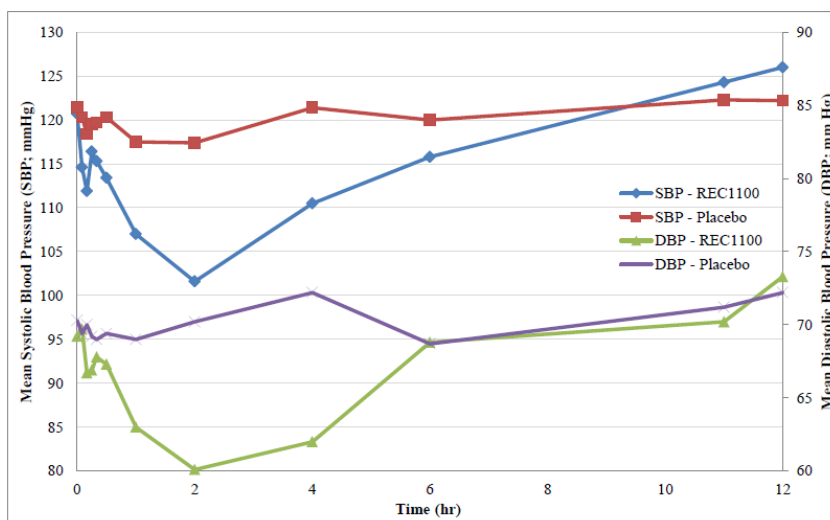
Source: Company documents

Exhibit 18: REC-09-003 - summary of AEs

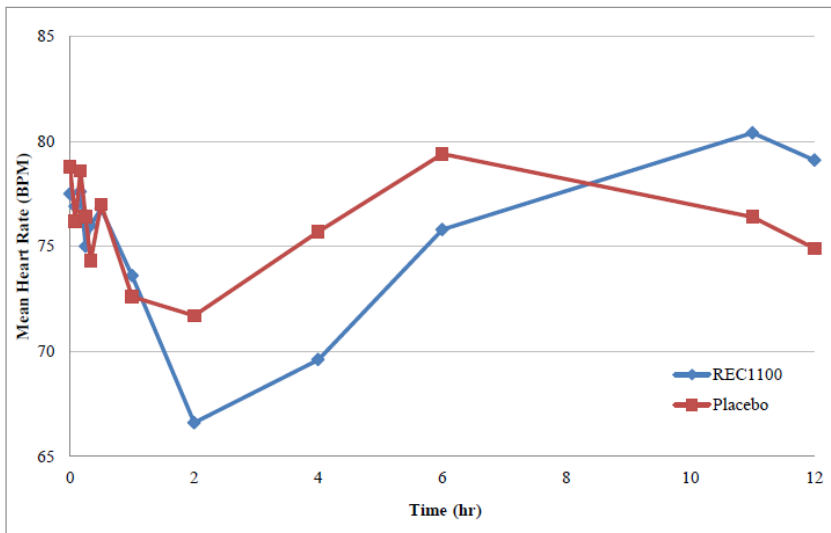
MedDRA System Organ Class / Preferred Term	Crossover Phase		Repeated Dose Phase	
	REC1100 (N = 21)	Placebo (N = 21)	Non-Opioid (N = 12)	Opioid (N = 9)
Cardiac Disorders	0	0	1	0
Bradycardia	0	0	1	0
Gastrointestinal Disorders	3	1	2	1
Abdominal Pain	0	0	0	1
Dry Mouth	1	0	1	0
Parasthesia Oral	1	0	0	0
Tongue Ulceration	0	0	1	0
Vomiting	1	0	0	0
Musculoskeletal and Connective Tissue Disorders	1	0	0	0
Arthralgia	1	0	0	0
Nervous System Disorders	6	2	5	3
Dizziness	2	0	2	2
Dysgeusia	1	0	0	0
Headache	1	1	1	1
Hypoaesthesia oral	0	0	1	0
Migraine	1	1	1	0
Somnolence	1	0	0	0
Skin and Subcutaneous Tissue Disorders	1	0	0	0
Petechiae	1	0	0	0
Vascular Disorders	2	0	2	2
Hypotension	2	0	0	1
Orthostatic Hypotension	0	0	2	1

Source: Company documents

Exhibit 19: REC-09-003 - mean blood pressure (systolic and diastolic) in the cross-over phase

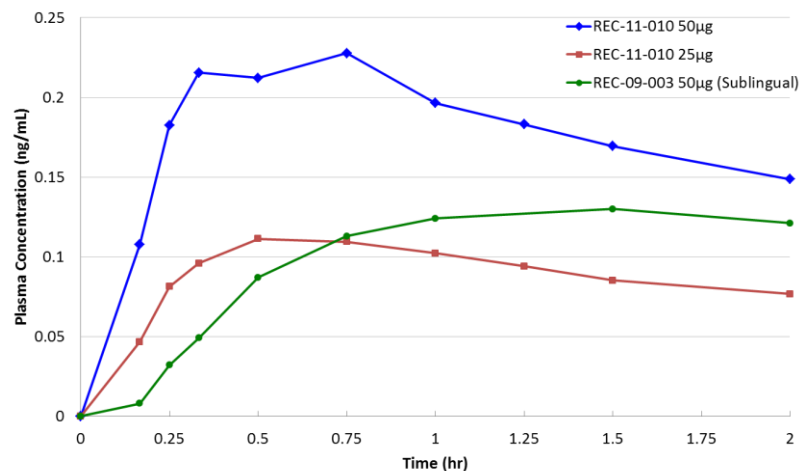


Source: Company documents

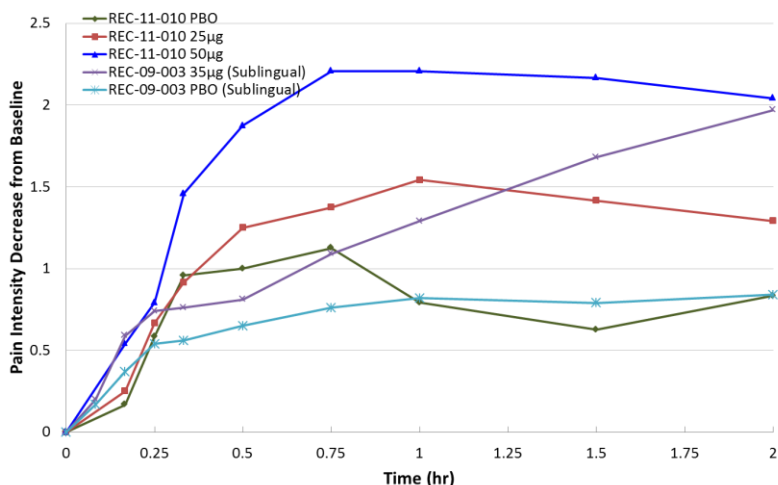
Exhibit 20: REC-09-003 - mean heart rate in the cross-over phase

Source: Company documents

Comparison of REC-11-010 with REC-09-003. When comparing the pharmacokinetics and efficacy of Dex-IN with that of Dex-SL, we note that at the same dose level of 50µg, Dex-IN showed a quicker onset of action and higher plasma concentration than Dex-SL, and that Dex-IN resulted in greater reduction in pain intensity than Dex-SL. As a result, Recro decided to pursue Dex-IN first, and views Dex-SL as a candidate for subsequent development for chronic pain following its initial focus on Dex-IN, a wise strategy, in our view.

Exhibit 21: REC-11-010 vs. REC-09-003 - mean dex plasma concentration

Source: Company documents

Exhibit 22: REC-11-010 vs. REC-09-003 – pain intensity difference

Source: Company documents

REC-11-008 Chronic Pain Trial of Multi-Dose Dex-IN

REC-11-008 evaluated the safety of repeated dosing of Dex-IN 35µg. Seven 35µg doses of Dex-IN were given to 12 healthy volunteers every six hours. AEs reported by patients were mild in severity and decreased in frequency over time upon repeated dosing. REC-11-008 involved voluntary AE reporting, by contrast to REC-11-010, where patients were asked every 15 minutes if they were experiencing any of several key AEs and which likely explains the higher AE incidence in REC-11-010. Vital signs including heart rate and blood pressure were evaluated every 5 minutes for two hours after dosing. Changes in vital signs were consistent with that observed in previous trials and decreased in magnitude with repeated dosing. Nasal irritation was not common and was mild when reported. There was also a low degree of sedation.

Exhibit 23: REC-11-008 – AEs

Term	Number of Subjects									
	Period 1 n = 12		Period 2 n = 10							Total
	D1 7am	D2 1pm	D1 7am	D2 1pm	D3 7pm	D4 1am	D5 7am	D6 1pm	D7 7pm	
Back Pain	-	-	-	-	1	-	-	-	1	1
Muscle Spasms	-	-	-	-	-	-	-	-	-	1
Dizziness	-	1	2	-	-	-	-	-	-	3
Headache	-	-	-	1	-	-	-	-	-	1
Anxiety	-	-	1	-	-	-	-	-	-	1
Nasal Discomfort	-	3	-	5	-	-	-	-	-	6
Nasal Dryness	-	1	-	2	-	-	-	-	-	3
Rhinalgia	-	-	-	-	1	-	-	-	-	1
Rinorrhea	-	1	-	-	-	-	-	-	-	1

Source: Company documents

Exhibit 24: REC-11-008 – vital signs

<u>Term</u>	<u>Period 1</u> <u>n = 12</u>		<u>Period 2</u> <u>n = 10</u>							<u>Total</u>
	<u>D1</u>	<u>D2</u>	<u>D1</u>	<u>D2</u>	<u>D3</u>	<u>D4</u>	<u>D5</u>	<u>D6</u>	<u>D7</u>	
	7am	1pm	7am	1pm	7pm	1am	7am	1pm	7pm	
Hypotension	2	3	2	1	-	1	1	-	1	6
Bradycardia	2	3	4	-	1	-	-	-	1	6
Ortho. Hypotension	-	1	-	-	-	-	-	-	-	1

Source: Company documents

Fadolmidine (Fado)**History of Fado**

Recro's second drug candidate, fado, is another selective alpha-2 agonist which was evaluated in a post-bunionectomy Phase 2 trial. Like dex, fado is a full agonist of all subtypes of the alpha-2 adrenaline receptor; unlike dex, fado does not cross the blood brain barrier and therefore can be potentially used for either intrathecal administration for pain or anesthesia, or topical administration for regional nerve pain from underlying nerve damage (or neuropathies). Our valuation of Recro does not include fado, and thus success with this product represents potential upside.

Clinical Trials

Orion completed Phase 1 and Phase 2 trials with fado in a total of 130 patients. In a Phase 2 single-blind dose-escalation trial, various doses of fado (40, 60, 80, 100, 120, 140, 160, 180, 200, 220 and 240µg) were administered intrathecally with 5mg of bupivacaine to induce spinal anesthesia in patients undergoing bunionectomy surgery. Seven patients were enrolled at each dose level, where six patients were randomized to receive fado plus bupivacaine, and one patient received only bupivacaine 10mg. PCA morphine was available as rescue therapy.

As the fado dose increases, the time to first post-operative dose of PCA morphine becomes longer and the total morphine use in the first ten hours declines. In addition, doses of fado greater than 120µg appeared to suppress pain. Fado was well tolerated. Incontinence and bradycardia were observed only at 240µg, the highest dose studied. Although morphine use was reduced with fado, nausea and vomiting were more frequent with fado compared to bupivacaine 10mg alone. Fado was also associated with reductions in blood pressure, but did not appear to increase sedation.

Post-Operative Pain Market Opportunity

In the post-operative pain setting, acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), sodium channel blockers, and opioids are prescribed to relieve pain of various severities. While acetaminophen, NSAIDs, and sodium channel blockers are generally prescribed for mild to moderate pain relief, opioids are prescribed for moderate to severe pain relief and dominate the post-operative pain market given the often intense pain in

this setting. Opioids, including morphine, oxycodone, fentanyl, and tramadol, are usually delivered via intravenous, intramuscular, intrathecal, or epidural routes, by hospital personnel or with patient-controlled analgesia (PCA) devices. They provide adequate pain relief for sure, but are often associated with respiratory depression, cognitive impairment, and GI side effects of constipation, nausea, and vomiting. Constipation alone can cause an extra day or so in the hospital and hospitals are on the hook financially for patients that need to be readmitted due to complications related to their surgery. Opioids may also lead to opioid abuse/addiction, and for this reason they are regulated as controlled substances. By contrast, dex is an effective analgesic that is not subject to the side effects or any addictive potential associated with opioids, as it has no associated euphoria and no liking in abuse liability trials with recreational drug users. Also, dex does not cause respiratory depression and it reduces anxiety due to its anxiolytic properties. We expect Dex-IN to compete against opioids in moderate to severe pain, and believe its non-opioid nature and thus better safety profile should create a niche market.

In the U.S., about 51 million inpatient procedures were performed in 2010 and 53 million outpatient procedures were performed in 2006, based on estimates from the National Center for Health Statistics. Of these procedures, we believe about 40 million procedures require a post-operative pain medication such as Dex-IN and therefore represent the addressable market of Dex-IN. According to GBI Research, U.S. sales of post-operative pain drugs were about \$5.9 billion in 2010.

Exhibit 25: Pain relief options for patients

Pain Severity	Class	Compounds	Advantages	Disadvantages
Mild	Acetaminophen		Antipyretic properties; Oral; no opioid AEs	Only effective for mild pain
	NSAIDs	Ketorolac, ibuprofen, aspirin	Mild to moderate analgesia; oral; no opioid AEs	Bleeding risk; GI and renal complications
Moderate	Sodium channel blockers	Bupivacaine, lidocaine	Use directly at pain site; mostly peri-operative	Limited duration of action; some are concerned about local tissue impact
Severe	Alpha 2 agonists	Dexmedetomidine (Recro Pharma)	Good pain relief; anxiolytic properties; no respiratory depression, impaired GI or addictive properties	In development – potential for first in class to be approved for post-operative pain
	Opioids	Morphine, hydrocodone, oxycodone, fentanyl	Good pain relief	Respiratory depression, impaired GI motility after even one dose; frequent nausea and vomiting; abuse/addiction potential

Source: Company documents

Exhibit 26: Dex has significant advantages over opioids

Dex	Fast-acting Opioids
Non-opioid (Not controlled substance)	Opioid - DEA scheduled product
No habituation effects	Addictive
Does not cause respiratory depression	Respiratory depression
Not associated with constipation, nausea, or vomiting	Unwanted side-effects of constipation, nausea and vomiting
Enhances morphine effectiveness without morphine dose increase	Additive effect requires higher dose
More cognitively intact	Frequently “Foggy”/ may be confused
Anxiolytic properties	No anxiety reduction
Effective Analgesic	Effective Analgesic

Source: Company documents

Competitive Landscape

In the post-operative pain setting, we believe Dex-IN will be used for moderate to severe pain, competing primarily against opioids. Given Dex-IN’s intranasal delivery and non-opioid nature, we identified drugs or drug candidates that either employ a convenient drug delivery (Zalviso and Sprix), or are abuse-deterrent opioids (CR845 and Egalet-001), as Dex-IN’s primary potential competitors.

Zalviso (Sufentanil NanoTab PCA System)

AcelRx’s Zalviso Sufentanil NanoTab PCA System is a novel patient-controlled sublingual analgesia (PCSA) product candidate with a pre-programmed patient lock-out feature that is designed to manage moderate to severe acute pain in hospital settings. Zalviso’s active ingredient, sufentanil, is a high therapeutic index opioid approved for intravenous and epidural administration. The NDA for Zalviso 15µg was accepted by the FDA in November 2013, with FDA decision expected in 4Q14.

Exhibit 27: Zalviso Sufentanil NanoTab PCA System

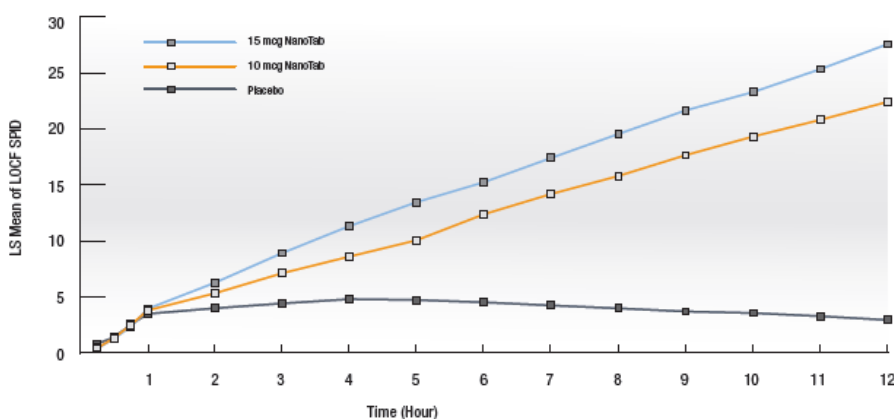
Source: AcelRx company documents

Two Phase 3 trials of 15µg Zalviso, one in patients following open abdominal surgery and the other in patients following knee or hip replacement surgery, showed that Zalviso relieved post-operative pain in these patients, as measured by the 48-hour summed pain intensity difference (SPID-48), which is a time-weighted summed pain intensity difference over the 48-hour period compared to baseline, and also the primary endpoint to be used in the next Dex-IN trial.

Results from two Phase 2 trials, one in patients following major abdominal surgery and the other in patients following elective unilateral knee replacement surgery, showed that Zalviso significantly reduced pain intensity as measured by the 12-hour summed pain intensity difference (SPID-12), which is a cumulative measure of the difference in pain intensity over the 12-hour period compared to baseline. We note that Dex-IN showed in its Phase 1b trial a solid separation in SPID versus placebo as early as one hour post-dosing, whereas the difference in SPID was not clear for Zalviso at one hour post-dosing, suggesting that Dex-IN may potentially be a more effective analgesic with quicker onset of action.

In one Phase 2 trial, 92 patients following major abdominal surgery were randomized to receive placebo, 10µg or 15µg doses of Zalviso after stabilization of pain levels in the post-operative care unit. Zalviso was nurse administered sublingually at the patient's request, with a minimum re-dosing interval of 20 minutes. Compared to placebo, both doses of Zalviso significantly reduced the pain intensity ($p<0.01$) and resulted in a lower percentage of patient dropouts due to inadequate analgesia ($p<0.001$). There were no drug-related SAEs, and the most common AE was nausea, which occurred with similar frequency in all treatment arms.

Exhibit 28: SPID-12 of Zalviso for pain following major abdominal surgery

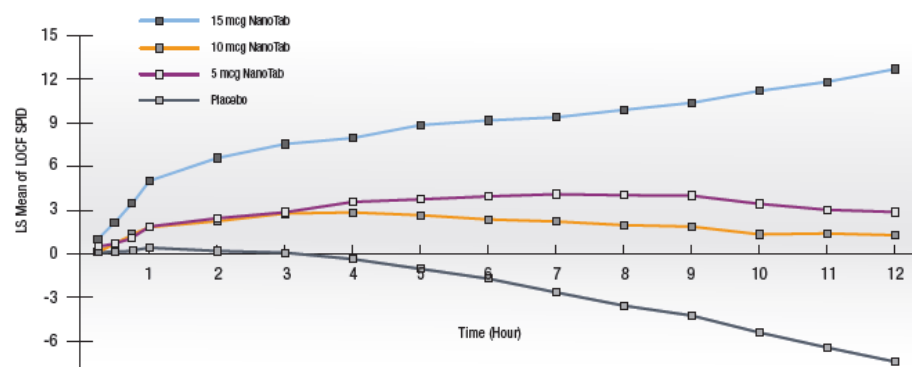


Source: AcelRx poster presentation at the 35th Annual Regional Anesthesia Meeting of the American Society of Regional Anesthesia and Pain

In another Phase 2 trial, 101 patients following elective unilateral knee replacement were randomized to receive placebo, 5µg, 10µg or 15µg doses of Zalviso after stabilization of pain levels in the post-operative care unit. Zalviso was nurse administered sublingually at the patient's request, with a minimum re-dosing interval of 20 minutes. Only the 15µg

Zalviso significantly reduced the pain intensity compared to placebo and reported a lower percentage of patient dropouts due to inadequate analgesia compared to placebo. There were no drug-related SAEs, and the most common AE was nausea, which occurred with similar frequency in all treatment arms.

Exhibit 29: SPID-12 of Zalviso for pain following knee replacement surgery



Source: AcclRx poster presentation at the 35th Annual Regional Anesthesia Meeting of the American Society of Regional Anesthesia and Pain

CR845 (Kappa Agonist)

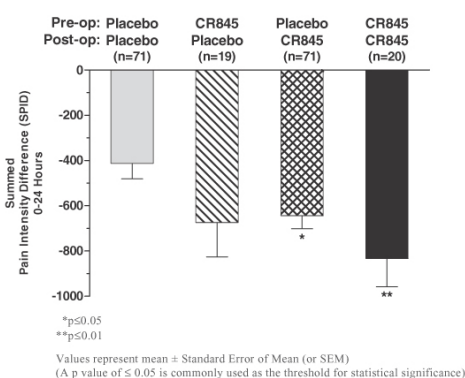
Cara Therapeutics' peripheral kappa agonist, CR845, is highly selective for kappa opioid receptors present on peripheral pain-sensing nerves. CR845 does not well penetrate the blood-brain barrier and therefore causes fewer CNS-mediated side effects than centrally-acting mu opioids. In animal models, CR845 was not shown to inhibit intestinal transit (ileus), induce serious respiratory depression, or elicit addiction or euphoria. The IV formulation of CR845 is being developed for post-operative pain while the oral formulation of CR845 is being developed for chronic pain.

Cara plans to initiate in 2H14 a Phase 3 program with IV CR845 for post-operative pain in a hospital setting. The FDA requires two Phase 3 trials, one in patients following soft tissue surgery and one in patients following hard tissue surgery, with primary endpoints being change in SPID at either 24 or 48 hours. Cara also plans to conduct an optional Phase 3 trial with IV CR845 dosed both pre-surgery and post-surgery in patients undergoing either laparoscopic hysterectomy or bunionectomy surgery. In all three trials, morphine will be available as rescue therapy. Should Dex-IN succeed in Phase 3 trials, its dosing advantage to CR845 is clear, from the perspective of the patient, the increased risk to a hospital of IV versus something far less invasive, and the ease of outpatient use.

IV CR845 was evaluated in three Phase 2 trials in post-operative pain, of which two were conducted in patients following laparoscopic hysterectomy surgery and one in patients following bunionectomy surgery. A proof-of-concept Phase 2a trial of IV CR845 was conducted in patients undergoing laparoscopic hysterectomy. In a cohort of patients who received a single dose of IV CR845 0.04mg/kg or placebo within three hours following recovery from surgery, IV CR845 significantly lowered the pain intensity up to six hours post-infusion versus placebo, and also reduced the use of PCA morphine by 49% starting

at four hours post-infusion and lasting through an additional 12 hours. Based on the Phase 2a results, Cara initiated a larger Phase 2b trial of IV CR845 in 203 patients undergoing laparoscopic hysterectomy. All 203 patients were randomized to receive IV CR845 0.04mg/kg or placebo pre-surgery, and 183 patients were re-randomized to receive IV CR845 0.04mg/kg or placebo post-surgery. Accordingly, four treatment arms were formed, which were denoted as CR845/CR845, placebo/CR845 (a single post-surgery dose of CR845), CR845/placebo (a single pre-surgery dose of CR845), and placebo/placebo. The CR845/CR845 arm exhibited the largest reduction in summed pain over a 24-hour period (SPID0-24) that was statistically significant compared to the placebo/placebo arm ($p < 0.01$). The placebo/CR845 arm also exhibited a statistically significant improvement in SPID0-24 compared to the placebo/placebo arm ($p < 0.05$). The CR845/placebo arm exhibited a numerical improvement in SPID0-24.

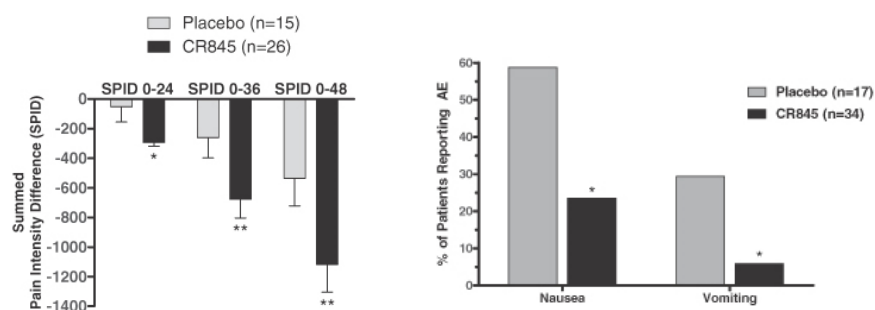
Exhibit 30: Phase 2b laparoscopic hysterectomy trial of IV CR845 – SPID0-24



Source: Cara Therapeutics document

In a Phase 2 trial of 0.005mg/kg IV CR845, 51 patients undergoing bunionectomy surgery were randomized 2:1 to receive an initial bolus dose of IV CR845 or placebo, and again 30-60 minutes later at the patient's request, and thereafter up to every 8 hours at the patient's request (until hour 40) over a 48-hour dosing period. Fentanyl was allowed if pain was not adequately relieved. In the completer analysis, IV CR845 achieved a statistically significant reduction in pain intensity over the initial 24-hour period and over the entire 48-hour dosing period, as measured by the SPID0-24 and SPID0-48 scores. In addition, IV CR845 reduced the incidence of opioid-related adverse events of nausea and vomiting (by 60% and 80%, respectively; $p < 0.05$) compared to placebo during the entire 48-hour treatment period.

Exhibit 31: Phase 2 bunionectomy trial of IV CR845 – SPID0-24 SPID0-36 and SPID0-48 in completer population, CR845 suppression of nausea and vomiting



Source: Cara Therapeutics document

Egalet-001 (ER Morphine)

Egalet is developing an abuse-deterrent extended-release oral morphine (Egalet-001) and oral oxycodone (Egalet-002) for moderate to severe pain. There are currently no commercially available abuse-deterrent formulations of morphine. Egalet evaluated Egalet-001 in Phase 1 PK trials and plans to initiate in 1Q14 pivotal trials that establish the bioequivalence of Egalet-001 to MS-Contin, an approved oral controlled release morphine, with NDA submission expected in 4Q14. In addition, Egalet completed Phase 1 PK trials and initial abuse deterrence studies of Egalet-002, and the company plans to initiate the first of two Phase 3 trials for Egalet-002 in 4Q14 with NDA submission expected in 1H16.

Sprix (Ketorolac Tromethamine)

Sprix (ketorolac tromethamine) nasal spray is an intranasal NSAID approved by the FDA in 2010 for short-term (up to 5 days in adults) management of moderate to moderately severe pain. Although other formulations of ketorolac tromethamine (oral and injectable) have been marketed for many years for the short-term relief of pain, the intranasal formulation of ketorolac is the first and only intranasal NSAID because other NSAIDs cannot exist in a soluble form due to their chemical properties. Sprix can cause GI (ulceration and perforation), bleeding, and renal complications, which are common risks associated with NSAIDs. Should Dex-IN succeed in Phase 3 trials, it should have a safety advantage compared to Sprix.

Sprix was shown to effectively relieve post-operative pain in two randomized double-blind Phase 3 trials, one in patients following major orthopedic or abdominal surgery (n=300), and the other in patients following major abdominal surgery (n=321). Patients were randomized 2:1 to receive Sprix or placebo, either every 8 hours in the first trial or every 6 hours in the second trial for up to 5 days. A patient controlled analgesia (PCA) regimen using morphine was allowed in both trials if pain was not adequately relieved. The primary efficacy endpoint was the 6-hour summed pain intensity difference (SPID-6), but was later changed to SPID-24 and SPID-48 per FDA request. Morphine use was also assessed.

In the first Phase 3 trial, SPID-6 was significantly higher in the Sprix arm than in the placebo arm (83.3 vs 37.2, p<0.007), and morphine use was reduced by 34% in the Sprix

arm compared to the placebo arm. In the second Phase 3 trial, SPID-6 was also significantly higher in the Sprix arm (117.4 vs 89.9, $p=0.032$), and morphine use over 48 hours decreased by 26% in the Sprix arm compared to placebo ($p=0.004$).

Exhibit 32: Sprix nasal spray in a 5-bottle box



Source: Sprix company documents

Intellectual Property

In August 2008, Recro in-licensed worldwide (except Europe, Turkey, and the Commonwealth of Independent States or CIS) rights of non-injectable formulations of dex from Orion. The non-injectable formulations include transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, and exclude injection or infusion. The initial term of the license is 15 years and can be extended thereafter. As part of the transaction with Orion, Recro is entitled to have almost half of its total R&D spend on a given dex formulation reimbursed sometime after Phase 3 is complete, if and only if Orion wishes to commercialize that formulation in its territories, a feature that we find very attractive to the story. Orion just received approval in many of its territories so there is 10 years of exclusivity from which to benefit with any effective formulation of dex. Under the license agreement, Recro will make milestone payments to Orion of up to 20.5 million Euros upon regulatory approval of non-injectable dex and upon certain sales milestones. Recro will also pay Orion a tiered royalty on net sales at varying percentages from 10% to 20%. Recro is entitled to reference all regulatory filings made by Orion related to dex, dex products or the dex API.

In July 2010, Recro in-licensed worldwide (except Europe, Turkey, and the Commonwealth of Independent States or CIS) rights of fado from Orion. The initial term of the license is 15 years and can be extended thereafter. Under the license agreement, Recro will make milestone payments to Orion of up to 12.2 million Euros upon regulatory approval of fado and upon certain sales milestones. Recro will also pay Orion a tiered royalty on net sales at varying percentages from 10% to 15%. Recro is entitled to reference all regulatory filings made by Orion related to fado.

Recro and Orion also entered into a separate API agreement, where Orion agrees to provide Recro API for the development and commercialization of the dex and fado product candidates. During the pre-approval development period, Orion will provide API without charge for mutually-agreed amounts; any amounts ordered by Recro that are greater than the planned supply will be charged at 50% of the supply price for commercial product. Upon commercialization, Recro will provide a rolling forecast of projected supply requirements to Orion, which will be updated on a quarterly basis for eight quarters.

The composition of matter patent (U.S. #4,910,214) for dex expired in mid-January 2014, allowing generic Precedex to enter the U.S. market by YE14. The composition of matter patent (U.S. #6,313,311) for fado expires on October 2, 2016 with a possible patent term extension under the Hatch-Waxman Act. Recro also in-licensed method of use patents for both dex and fado from Orion. In addition, Recro is pursuing three families of patents respectively for its sublingual (U.S. application serial No. 12/781,628), topical/transdermal (U.S. application serial No. 13/520,959), and intranasal (U.S. application serial No. 13/711,407) formulations of dex, with potential protection for its dex product candidates through 2030. The three dex patent application families are in various stages of prosecution, and no patent has been issued to date. If successfully issued, each patent family would cover the methods of treating or preventing pain without sedation via a specific formulation of dex, analgesic pharmaceutical compositions comprising dex, as well as dispensing devices containing dex related to a specific formulation.

Financials

Revenue. All projected revenue is due to Dex-IN sales in the U.S. for post-operative pain relief. Potential sales from the next potential Dex-IN indication, cancer breakthrough pain relief, would represent upside to our revenue forecast. For modeling purposes, we assume Recro commercializes Dex-IN itself, and therefore our model excludes potential upfront license fees and milestone payments. A successful Phase 2b trial of Dex-IN for patients following bunionectomy surgery however, would likely garner the attention of a potential partner, and could even result in the acquisition of Recro. We model a treatment cost of \$800 for a regimen consisting of four doses of Dex-IN per day for seven days, in line with the treatment cost of a branded oral opioid. Also, we are projecting Dex-IN to begin selling in late 2017 in the U.S. and to generate product revenue of \$222 million in 2020. Should Recro go on to pursue the cancer breakthrough pain indication with Dex-IN in 2016, we believe the peak year sales from this indication would be as large as the peak year sales from the post-operative pain indication.

Expenses. We project COGS for Dex-IN to be around 20%, including a low double-digit royalty to Orion which would constitute most of the COGS. Net proceeds of \$31.5 million raised from Recro's recent IPO will be used to support the company's R&D activities (\$16.6 million) and SG&A activities (\$14.9 million) through 2H15. Specifically, Recro expects to spend \$2.1 million for its Phase 2b trial with Dex-IN, \$8 million for its two Phase 3 trials with Dex-IN, \$1.5 million for preclinical animal toxicology studies, and \$5 million for human safety clinical trials. An NDA filing would cost about \$2.5 million. We believe most of this R&D spend will occur in 2015, when Phase 3 trials with Dex-IN are expected to be conducted. Recro currently has 6 employees, compensated at an annual rate of around \$200,000 per person. The company intends to recruit 50-70 sales reps upon Dex-IN approval for post-operative pain relief. We project SG&A expense to jump in 2014 and continue to increase thereafter as Recro ramps up for the launch of Dex-IN in 2017. Should Recro go on to pursue the cancer breakthrough pain indication with Dex-IN in 2016, we expect the costs of Phase 2 and Phase 3 trials as well as NDA filing to be \$15 million, and the additional SG&A spend to be \$8 million as Recro would need to hire another 30-40 sales reps for cancer breakthrough pain. Following its IPO in March, Recro no longer has any debt outstanding, and therefore we are not modeling any interest expense thereafter.

Bottom Line. We project Recro to be profitable in 2017, its first commercial year, due primarily to Dex-IN sales in the U.S. and a relatively low overall expense burden. We are not projecting income tax payments until 2019 due to projected NOLs. Following its IPO in March, Recro expects to have about 7.1 million shares outstanding, or about 7.7 million assuming the full exercise of underwriters' option to purchase 562,500 additional shares to cover over-allotments. The diluted share count takes into consideration outstanding warrants and options, including 334,800 shares issuable upon the exercise of options at \$6, 181,026 shares issuable upon the exercise of options at \$8, 140,000 shares issuable upon the exercise of options granted to seven board members at \$8, as well as 150,000 shares issuable upon the exercise of warrants granted to the lead underwriter at \$12.

Balance Sheet. Recro had about \$13,000 in cash at YE13, and added net proceeds of \$31.5 million from its IPO. The company's current cash position should be sufficient to support its operations through 2H15. Also, Recro no longer has any debt outstanding following its IPO in March. We expect significant stock price appreciation after the release of what we anticipate will be positive results from the Phase 2b trial of Dex-IN in patients undergoing bunionectomy surgery in late 2014.

Risks

- **Clinical risk.** Dex-IN and Dex-SL could fail to deliver statistically significant results in late-stage clinical trials, substantially reducing the value of Recro and our target price.
- **Regulatory risk.** Dex-IN and Dex-SL, even if successful in the clinic, could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce Recro's value and our target price.
- **Financing risk.** Recro does not have enough capital to fund its operations into 2016, and thus is reliant on obtaining additional outside funding, which may not occur or which could be substantially dilutive to existing investors.
- **Competitive risk.** Even if Dex-IN and Dex-SL are approved, they may not be well adopted by the marketplace, which would adversely affect Recro's value and our target price.
- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.

RECRO PHARMA, INC														
Income Statement														
Fiscal Year ends December														
(All amounts in 000s except per share items)														
	2011A	2012A	2013A	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Dex-IN for post-operative pain (US)								-	-	-	52,983	110,787	173,742	222,014
Total revenues				-	-	-	-	-	-	-	52,983	110,787	173,742	222,014
COGS											10,597	22,157	34,748	44,403
R&D	1,828	542	544	272	1,087	2,175	2,609	6,143	11,672	12,255	13,481	14,829	16,312	17,943
SG&A	485	339	546	683	1,024	1,434	1,864	5,004	8,006	12,810	25,620	35,867	50,214	60,257
Total operating expenses	2,313	881	1,090	954	2,111	3,608	4,473	11,147	19,678	25,065	49,697	72,854	101,275	122,603
Operating income (EBIT)	(2,313)	(881)	(1,090)	(954)	(2,111)	(3,608)	(4,473)	(11,147)	(19,678)	(25,065)	3,286	37,934	72,468	99,411
Interest income		0	0	30	79	71	64	243	268	295	324	356	535	802
Grant income		85						-	-	-	-	-	-	
Interest expense	(558)	(740)	(868)	(750)				(750)						
Income before taxes	(2,871)	(1,537)	(1,958)	(1,674)	(2,032)	(3,537)	(4,409)	(11,653)	(19,410)	(24,771)	3,610	38,290	73,002	100,213
Provision for income taxes			-					-	-	-	-	-	7,300	30,064
Net income, GAAP	(2,871)	(1,537)	(1,958)	(1,674)	(2,032)	(3,537)	(4,409)	(11,653)	(19,410)	(24,771)	3,610	38,290	65,702	70,149
Accretion of redeemable convertible preferred stock	(383)	(413)	(440)					-						
Net income to common shareholders	(3,254)	(1,949)	(2,398)	(1,674)	(2,032)	(3,537)	(4,409)	(11,653)	(19,410)	(24,771)	3,610	38,290	65,702	70,149
EPS basic	\$ (20.91)	\$ (12.53)	\$ (15.41)	\$ (0.36)	\$ (0.26)	\$ (0.45)	\$ (0.56)	\$ (1.66)	\$ (1.76)	\$ (2.21)	\$ 0.32	\$ 3.28	\$ 5.51	\$ 5.77
EPS diluted, GAAP	\$ (20.91)	\$ (12.53)	\$ (15.41)	\$ (0.36)	\$ (0.26)	\$ (0.45)	\$ (0.56)	\$ (1.66)	\$ (1.76)	\$ (2.21)	\$ 0.29	\$ 3.07	\$ 5.17	\$ 5.41
Basic shares outstanding	156	156	156	4,645	7,708	7,785	7,863	7,000	11,008	11,228	11,452	11,681	11,915	12,153
Diluted shares outstanding	156	156	156	4,645	8,513	8,590	8,668	7,604	11,813	12,033	12,257	12,486	12,720	12,958
Source: Company documents and Brean Capital, LLC. estimates														

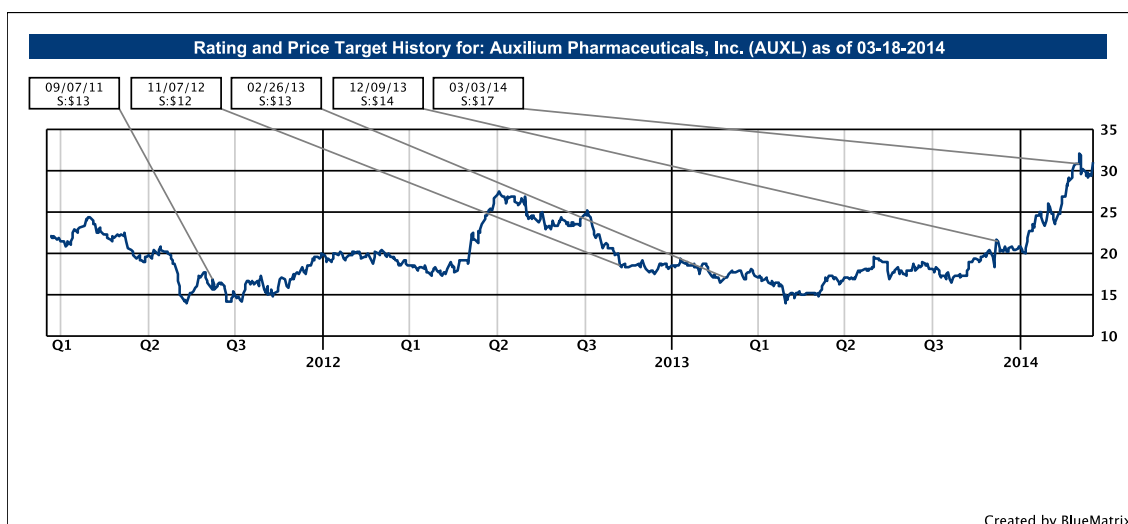
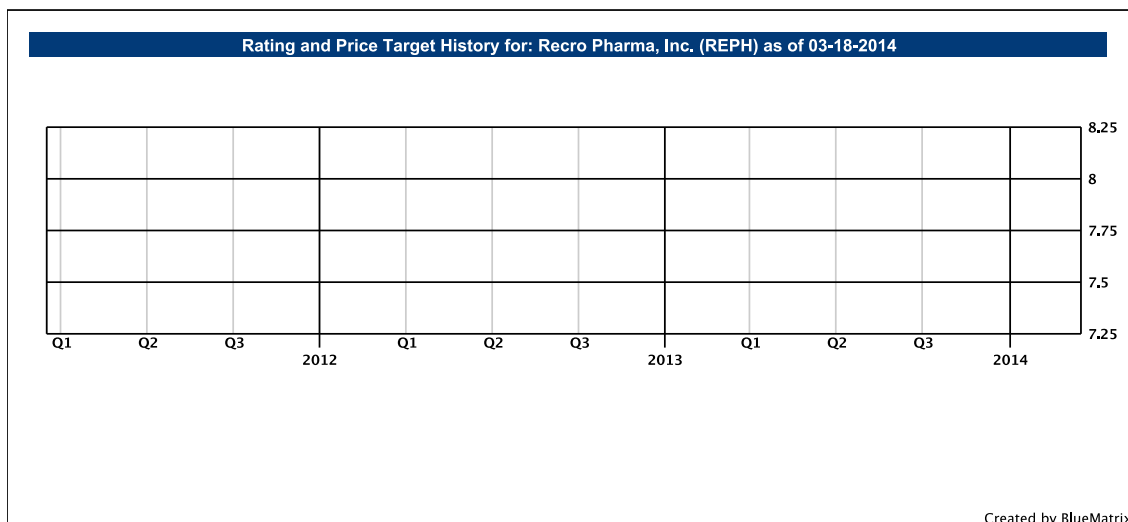
RECRO PHARMA, INC								
Balance Sheet								
Fiscal Year ends December								
(All amounts in 000s except per share items)								
	2011A	2012A	2013A	1Q14E	2Q14E	3Q14E	4Q14E	2014E
Current assets:								
Cash and cash equivalents	8	53	13	29,838	27,806	24,269	19,859	19,859
Other receivables		85	38					-
Deferred offering costs			784					-
Prepaid expenses	14	14	16	16	16	16	16	16
Total current assets	22	153	851	29,854	27,822	24,285	19,875	19,875
Equipment, net	3	1	-					-
Total assets	26	154	851	29,854	27,822	24,285	19,875	19,875
Current liabilities:								
Convertible notes payable	8,148	10,159	11,907					-
Accounts payable	195	16	434	400	400	400	400	400
Accrued expenses	267	102	590	17,590	17,591	17,591	17,590	17,590
Total current liabilities	8,610	10,276	12,931	17,990	17,991	17,991	17,990	17,990
Total liabilities	8,610	10,276	12,931	17,990	17,991	17,991	17,990	17,990
Commitments								
Series A redeemable convertible preferred stock, \$0.01 par value. Authorized, 2,000,000 shares; issued and outstanding, 2,000,000 shares (liquidation value of \$5,880,037 as of December 31, 2013)	5,027	5,440	5,880	5,880	5,880	5,880	5,880	5,880
Stockholders' equity (deficit):								
Preferred stock, \$0.01 par value. Authorized, 2,000,000 shares; none issued and outstanding								-
Common stock, \$0.01 par value. Authorized, 5,000,000 shares; issued and outstanding, 155,600 shares at December 31, 2012 and 2013, 2,796,117 shares at December 31, 2013 pro forma	4	2	2	38	38	38	38	38
Additional paid-in capital				31,462	31,462	31,462	31,462	31,462
Deficit accumulated during the development stage	(13,616)	(15,563)	(17,961)	(19,636)	(21,668)	(25,206)	(29,615)	(29,615)
Total stockholders' equity (deficit)	(13,612)	(15,562)	(17,960)	11,864	9,831	6,294	1,885	1,885
Total liabilities and stockholders' equity (deficit)	26	154	851	35,734	33,702	30,165	25,755	25,755

RELATED COMPANIES

Company	Ticker	Rating	Price
Auxilium Pharmaceuticals, Inc.	AUXL	Sell	31.01

Important Disclosures

Ratings and Target Price History



At the time this report was published, Brean Capital, LLC made a market in the securities of Recro Pharma, Inc. and Auxilium Pharmaceuticals, Inc. .

Recro Pharma, Inc. is, or within the last 12 months has been, a client of Brean Capital, LLC, and investment banking and/or advisory services are being, or have been provided.

Brean Capital, LLC has managed or co-managed a public offering or placement of securities of Recro Pharma, Inc. within the past 12 months.

Brean Capital, LLC expects to receive compensation for investment banking and/or advisory services from Recro Pharma, Inc. within the next 3 months.

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Brean Capital, LLC Stock Rating System

Buy - Expected to appreciate by at least 10% within the next 12 months.

Hold - Fully valued, not expected to appreciate or decline materially within the next 12 months.

Sell - Expected to decline by at least 10% within the next 12 months.

Rating Category	Count	Percent	IB Serv./ Past 12Mos.	
			Count	Percent
BUY	145	70.39%	17	11.72%
HOLD	54	26.21%	2	3.70%
SELL	7	3.40%	0	0.00%
NOT RATED				

Note: Stock price volatility may cause temporary non-alignment of some ratings with some target prices.

Analyst Certification

We, Jonathan Aschoff and Yi Cheng, hereby certify that the views expressed in this research report accurately reflect our personal views about any and all of the subject securities or issuers referred to in this document. The analyst and associate analyst further certify that they have not received and will not be receiving direct or indirect compensation in exchange for expressing the recommendation contained in this publication.

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