AEGIS CAPITAL CORP

Pharmaceuticals
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Initiating Coverage

June 12, 2014

Recro Pharma, Inc.

Rating: Buy

Driving The Dynamism Of Dexmedetomidine

Key Metrics

REPH - NASDAQ	$7.28
Pricing Date	Jun 11 2014
Price Target	$40.00
52-Week Range	$9.88 - $5.01
Shares Outstanding (mm)	7.7
Market Capitalization ($mm)	$56.1
3-Mo Average Daily Volume	47,219
Institutional Ownership	NM
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$3.82
Price/Book	1.9x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: December

	2014E	Prior 2015E	Curr. 2015E	Prior 2016E	Curr. 2016E
1Q-Mar	(3.67)A	--	(0.56)E	--	(0.56)E
2Q-Jun	(0.25)E	--	(0.56)E	--	(0.48)E
3Q-Sep	(0.44)E	--	(0.51)E	--	(0.44)E
4Q-Dec	(0.53)E	--	(0.55)E	--	(0.46)E
FY	(2.46)E	--	(2.18)E	--	(1.92)E
P/E	NM		NM		NM

Source: BigCharts.com

Company Description:
Recro Pharma, Inc. (http://www.recropharma.com/) is an emerging specialty pharmaceuticals firm focusing on the pain sector, based in Malvern, PA.

Investment Highlights:

- **Initiating Coverage.** We are initiating coverage on Recro Pharma, Inc. with a Buy rating and an 18-month price target of $40.00 per share. In our view, Recro represents one of the most risk-mitigated and undervalued companies in the development-stage specialty pharmaceuticals arena. The firm is developing two drug candidates, dexmedetomidine and fadolmidine, for the treatment of various pain indications. Recro's lead drug candidate, Dex-IN, is a proprietary intranasal formulation of dexmedetomidine that is scheduled to enter Phase 2b testing within the coming weeks. In our view, this drug could benefit from an accelerated pathway to approval via the 505(b)(2) regulatory route, since dexmedetomidine is already approved in the United States. The drug has been sold since approval in 1999 by Hospira, Inc. (HSP/ NYSE, Not Rated) as an intravenous formulation for sedation of patients in the intensive care unit (ICU) and post-operative settings, achieving peak sales of $150mm. We believe that the market opportunity for Dex-IN is substantially greater, with the potential to achieve $375mm in peak sales in the U.S. alone. In our view, Recro Pharma could deliver positive Phase 2b data with Dex-IN for treatment of pain associated with bunionectomy surgery in the U.S. by the end of this year, with Phase 3 development slated to begin and conclude next year. Dex-IN could be on the market by mid-2017.
- **Promising Specialty Pharmaceuticals Niche.** We note that the total market for painkillers targeting the post-operative pain space represents a $5.9bn market in the U.S. alone. This domain constitutes a significant unmet medical need, with opioid-based painkillers having significant abuse potential along with a litany of systemic side effects, including respiratory depression, constipation, nausea and vomiting. From our perspective, Recro Pharma's lead drug candidate provides a comparatively safe and well-tolerated alternative, with documented evidence of efficacy and a rapid onset of action. Dexmedetomidine also functions as a potent anxiolytic, enabling it to provide even more benefits to patients in the post-operative pain setting. Recro's sublingual formulation of the drug (Dex-SL), has already demonstrated positive impact in chronic pain, which could constitute an entirely new market for the company. Fadolmidine, which acts through a similar pathway to dexmedetomidine, has applicability in chronic pain (via topical administration) as well as acute pain (via intrathecal administration).
- **Solid Management With Proven Track Record At A Low Price.** We note that the Chief Executive Officer of Recro Pharma, Gerri Henwood, is a seasoned industry professional who also co-founded Auxilium Pharmaceuticals (AUXL/NASDAQ, Buy), now a $1bn market cap company. Further, we would draw investors' attention to the fact that Recro, with its risk-mitigated drug candidates and rapid path to market, currently trades at an enterprise value of under $25mm.

The Disclosure section may be found on pages 47 - 49 of this report.

Investment Thesis

Recro Pharma, Inc. is a specialty pharmaceuticals firm developing two compounds for the treatment of pain. The company is developing two novel formulations of dexmedetomidine (dex) – one that is intranasally-administered and another that can be dosed in a sub-lingual manner (under the tongue) – and is also developing a second pipeline candidate called fadolmidine (fado), which is considered a potential treatment for spinal analgesia and other peripheral pain conditions. Both dex and fado are agonists of the alpha-2 (α_2) adrenoreceptor, and were in-licensed by Recro Pharma from Orion Corporation. Precedex has been sold in the U.S. by Hospira for many years, generating roughly $150 million a year in sales. In our view, given the lengthy usage history of dex as an anesthetic agent in the U.S. and considering its well-characterized safety and efficacy profile, the clinical development programs that Recro envisages for this drug should have a high likelihood of success. We believe that Recro Pharma could successfully commercialize its proprietary formulations of dex in the U.S. market even given the context of Precedex's expected genericization over the course of 2014. Recro could file for approval of its intranasal formulation of the drug with data from two pivotal Phase 3 trial in addition to the results generated from a Phase 2b study that we expect the firm to complete this year. In our view, Recro Pharma could launch the intranasal formulation of dex by mid- to late 2017 and achieve profitability in either late 2017 or early 2018 based on sales of this drug alone. Further, since dex has been marketed for nearly 15 years as a sedative agent, we believe that Recro Pharma would be able to file for approval via the simplified 505(b)(2) pathway and would not be required to face an advisory panel vote prior to regulatory approval in the U.S. The firm's intranasal and sublingual formulations of dex are proposed to be covered by three families of U.S. patent applications that are projected to expire in 2030 without patent term extensions. We note that significant additional upside could come from the commercialization of the sublingual formulation of dex in more chronic post-operative pain management settings, as well as successful development and commercialization of fado.

We are initiating coverage on REPH with a Buy rating and an 18-month price target of $40.00 per share, implying a total firm value of $480mm, assuming 10mm shares outstanding as of end-2015. An investment in REPH may involve above-average risk and volatility, since the firm is still a development-stage entity.

Investment Positives

Risk-Mitigated Drug Profile. Dex, in our view, is one of the most risk-mitigated drug development opportunities in the specialty pharmaceuticals sector. The intravenous version has been approved since December 1999, has generated hundreds of millions of dollars in sales and is known to be effective for the same indication in which Recro Pharma aims to deploy its intranasal formulation. The dex dosage administered intravenously is roughly ten times higher than that projected to be administered intranasally, leading us to believe that the safety of Recro's formulation should be straightforward to demonstrate. In our view, the firm could potentially secure approval of dex in the U.S. by mid-2017.

Multiple Near-Term Value Drivers. Recro Pharma is slated to initiate a Phase 2b trial of dex in mid-2014; close enrollment in this trial in the third quarter of 2014; and release top-line data before year-end. We expect the firm to conduct two pivotal Phase 3 trials of dex during the course of 2015 and file for approval of the drug by mid-2016.

Capital-Efficient Business Model. As of March 31st, 2014, Recro Pharma had recorded an accumulated deficit of roughly $23 million since inception in November 2007. In our view, the fact that the firm has burned so little money since inception is extremely encouraging. We would point investors to the fact that management has guided towards

the cost of dex clinical development and filing as being under $30 million. In the recently-completed IPO on the NASDAQ Capital Market, Recro raised $34.5 million in gross proceeds (including the over-allotment, which was exercised in full). From our perspective, these funds should be sufficient to sustain operations through completion of the Phase 2b trial of dex in the U.S. and the subsequent pivotal studies.

Significant M&A Precedent. We would also draw investors' attention to the fact that there have been several recent M&A transactions in the specialty pharmaceuticals sector involving pain companies. In our view, if Recro Pharma can generate positive pivotal data with dex, it could potentially become the subject of an acquisition transaction involving one of the more-established specialty pharmaceuticals firms seeking to bolster their flagging pipelines. However, even if such a transaction never materialized, we believe that the seasoned Recro management team would be able to launch intranasal dex in the U.S. independently using a contract-based specialty sales force.

Investment Risks

Financial Outlook and History of Unprofitable Operations. Recro Pharma has incurred operating losses since inception and, in our view, may not achieve sustainable profitability for several years. Although the firm has been able to obtain capital in order to fund its operations, it is not known whether the company will be able to continue this practice, or be able to obtain other types of financing to meet operating needs. While the firm recently managed to raise $34.5 million in gross proceeds through an initial public offering (IPO) to support the advancement of its lead pipeline drug candidate in the U.S., which in our view removes any financing overhang for at least 12 – 15 months, we believe that any additional broadening of the clinical-stage pipeline could require additional capital. Furthermore, the company is expected to expend significant resources on the pivotal trial program for its lead candidate, intranasal dexmedetomidine. Recro Pharma would likely have to raise additional capital in order to support a regulatory filing and commercialization if it elects to launch the product independently. Given these factors, shares of Recro may constitute above-average risk and volatility, in our opinion.

FDA Unpredictability. Drug development is a multi-year process that requires human clinical trials prior to market entry. The agency may require more clinical data from Recro Pharma prior to granting approval for any of its regulatory applications, necessitating further trials. Review times at the FDA may prove longer than expected. Also, the agency could elect not to accept Recro Pharma's regulatory filings petitioning for approval of EVK-001. If clinical data and/or other supporting evidence are not accepted or considered insufficient grounds for approval, marketing authorization for Recro's only drug candidate could be delayed or might not occur at all, preventing the firm from realizing the commercial potential of its lead program.

Partnership Risk. Recro Pharma is focusing on clinical advancement of its lead drug candidate in post-operative pain management, while eschewing an emphasis – at least for the time being – on becoming a fully-integrated specialty pharmaceuticals company. The firm aims to either partner with an established company or launch its lead drug independently with a specialty sales force. This introduces several elements of risk from a partnering perspective – the possibility that the company's partnership deals may not involve terms that are lucrative enough to justify the investment that Recro has made in the development of its lead agent; the possibility that Recro's partners do not invest sufficiently in the commercialization of Recro's products; and the risk that the firm's partners may not be the best-positioned competitively to ensure maximal penetration of Recro's most advanced drug into their target markets. Furthermore, should Recro fail to attract a partner at all, the company would have to raise substantial additional capital to fund the establishment of a proprietary sales force or the hiring of a contract sales force. Such infrastructure may not be capable of supporting a successful launch.

Insufficient Diversification Risk. While we view Recro Pharma as a risk-mitigated investment opportunity because of the fact that intravenous dexmedetomidine has been approved and utilized by anesthesiologists and pain physicians for many years, we note that the firm does not have a pipeline beyond dexmedetomidine and fadolmidine, its orally-bioavailable adrenoreceptor agonist drug. Accordingly, therefore, if dexmedetomidine fails to show statistically significant efficacy and acceptable safety and tolerability in late-stage studies, Recro Pharma may find itself without strategic options.

Competitive Landscape. Recro Pharma is aiming to compete with other, more established firms within the pharmaceutical sector. Some of these competitors include Actavis, Novartis, and Pfizer. These companies all have drugs already on the market for various pain management conditions and many of their franchises are well-entrenched. In addition, these competitors may develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any products or processes that Recro Pharma may be capable of developing. Finally, there are likely to be several generic versions of intravenous dexmedetomidine already on the market by the time Recro completes clinical development of its intranasal formulation. Generic drug makers are likely to price aggressively in order to gain market share, which may make it difficult to establish a niche for intranasal dexmedetomidine.

Intellectual Property Risk. The company relies on patents and trade secrets to protect its products from competition. A court might not uphold Recro Pharma's intellectual property rights, or it could find that Recro infringed upon another party's property rights. We note that none of Recro's proprietary intellectual property on its own formulations of dexmedetomidine has been formally issued yet. The intravenous formulation of dexmedetomidine is slated to undergo genericization over the course of 2014. If Recro Pharma's pending patent application-based claims are never issued, generics firms could potentially easily find loopholes in Recro's intellectual property estate, which may enable them to launch generic versions of dexmedetomidine and fadolmidine and/or other pipeline candidates prior to the expiration of patent protection.

Reimbursement Risk. Following the institution of broad healthcare reform policy, reimbursement agencies have grown more wary of systematically reimbursing for drugs that are either unnecessary or provide marginal benefit at excessive cost. If Medicare spending growth continues to outpace GDP growth, and the government's ability to fund healthcare becomes impaired, changes could be made to reimbursement policy that would negatively affect Recro Pharma, despite what we believe to be the compelling value proposition inherent in the firm's formulations of dexmedetomidine and fadolmidine.

Additional Risks. Following its recent IPO in March 2014, Recro Pharma had about $29.9 million in cash and equivalents. While the firm is not projected to burn a significant amount of cash near-term, these estimates could change if the firm began developing additional candidates beyond the current pipeline or if the firm were to be required to perform further studies beyond the envisaged pivotal trials. Other sources of cash could include: licensing fees from partnerships, warrant and option exercises, or the issuance of more shares. If intranasal dexmedetomidine fails to demonstrate efficacy and safety in pivotal clinical development, Recro Pharma may not be able to raise cash at all.

Industry Risks. Emerging biotechnology and pharmaceuticals stocks are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and the stock price. We do not anticipate volatility subsiding in the near term.

For additional risk considerations, please refer to the company's SEC filings.

Valuation

Comparables Analysis: Since Recro Pharma is currently unprofitable and given our belief that sustainable profitability is some distance off, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, it appears the stock is worth $40.00 per share, utilizing our estimate of a ~$450 million risk-adjusted net present value (rNPV) for intranasal and sublingual dexmedetomidine in pain management, along with fadolmidine. This assumes that the shares trade in-line with the comps' present average enterprise value of ~$450 million and that the firm has ~12 million shares outstanding (fully-diluted) and ~$37 million in cash as of late 2015.

Table 1: Comparable Company Analysis
(Millions, Except Per-Share Data)

Development stage	Therapeutic focus	Company Name	Ticker	Rating	Closing price (06/11/14)	Shares (MM)	Market cap ($MM)	Cash ($MM)	Debt ($MM)	Enterprise value ($MM)
Pre-registration	CNS / Neuropsychiatry	ACADIA Pharmaceuticals	ACAD	Not Rated	$22.80	99	2257	369	0	1887
Phase 2 / 3	Pain / Ophthalmology	Ampio Pharmaceuticals	AMPE	Buy	$7.18	52	373	78	0	295
Phase 2 / 3	Various	Auspex Pharmaceuticals	ASPX	Not Rated	$20.82	23	474	120	14	368
Phase 2 / 3	Pain	Cara Therapeutics	CARA	Not Rated	$14.07	23	318	67	0	251
Marketed	Pain / CNS Disorders	DepoMed	DEPO	Not Rated	$13.22	58	767	208	0	558
Marketed	Infectious Diseases	Durata Therapeutics	DRTX	Not Rated	$15.86	27	423	42	25	406
Pre-registration	Pain	DURECT Corporation	DRRX	Not Rated	$1.43	111	158	18	0	140
Phase 1 / 2	Pain	Egalet Corporation	EGLT	Not Rated	$13.33	17	230	77	0	153
Phase 2	Pain	Flexion Therapeutics	FLXN	Not Rated	$12.72	16	199	79	5	125
Marketed	CNS Disorders	Horizon Pharma	HZNP	Not Rated	$15.24	73	1120	103	113	1129
Phase 3	Pain	Pain Therapeutics	PTIE	Not Rated	$5.60	46	255	47	0	208
Marketed	CNS / Pain / Generics	Pernix Therapeutics Holdings	PTX	Buy	$6.92	38	261	56	70	275
Marketed	CNS / Pain / Gastroenterology	Progenics Pharmaceuticals	PGNX	Not Rated	$3.86	70	269	94	0	174
Phase 3	Cosmeceuticals	Revance Therapeutics	RVNC	Not Rated	$30.39	19	568	88	14	494
Marketed	Pain	Zogenix	ZGNX	Not Rated	$1.78	140	248	51	29	227
		Average					**529**			**450**
								Discrepancy		
Current valuation	**Pain**	**Recro Pharma Inc.**	**REPH**	**Buy**	**$7.28**	**8**	**56**	**30**	**0**	**26**
					Derived 18-month target price					**Projected**
Target valuation (18-month)	**Pain**	**Recro Pharma Inc.**	**REPH**	**Buy**	**$40.00**	**12**	**490**	**37**	**0**	**450**

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We estimate that Recro Pharma is likely to be free cash flow negative for the foreseeable future. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our $60.00 price target. This approach is described further in the next section of the report.

Our detailed analysis is split into five principal components – our discounted cash flow model including the rNPV assessment of both the intranasal and sublingual formulations of dexmedetomidine as well as the oral formulation of fadolmidine (presented overleaf); our assessment of the market for this agent and the associated sales model for the drug; the residual value of dexmedetomidine's potential applicability in other pain indications; and the near-term financial outlook for the company. Our historical income statement and financial projections are presented at the back of this report.

Risk-Adjusted Net Present Value Analysis

We have computed a risk-adjusted Net Present Value (rNPV) assessment of Recro Pharma's pipeline – consisting of the adrenoreceptor-modulating drugs dexmedetomidine and fadolmidine – in order to derive our fundamental valuation of the company. As shown below, our rNPV analysis yields a total of $400 million, or approximately $33 per share, for the two formulations of dexmedetomidine – namely, Dex-IN and Dex-SL – being developed by Recro. The firm's other pipeline candidate, fadolmidine, contributes $50 million. We are projecting that Dex-IN and Dex-SL could be launched in the 2017 – 2019 time frame, with fadolmidine potentially entering the market in the 2019 / 2020 time frame. As per the licensing agreement terms to which Recro assented, we have modeled only sales in the U.S. and in certain ex-U.S. markets, such as Canada, Australia and certain Latin American countries. We assume that the U.S. market represents the lion's share of the global opportunity that Recro Pharma has the right to target.

Table 2: Composite Risk-Adjusted Net Present Value Analysis

Dex-IN / Dex-SL Formulations - Global	
Total post-operative pain patients[1]	100MM
Patients seeking treatment[2]	12MM
Peak market share[3]	12%
Treatment revenue/prescription/course of therapy[4]	$30
Peak sales[5]	$427MM
Launch[6]	2017 / 2019
Peak sales year	2023 / 2027
Protection expires[7]	2030
Discount rate	15%
Probability of success[8]	85%
Risk-adjusted NPV[9]	$400MM
NPV per share	$33.00
Estimated Net Cash Position ($MM; end-2015)	$37MM
Additional Value Drivers (fadolmidine)	$50MM
Total enterprise value	$487MM
Shares Outstanding (MM; end-2015)	12MM
Present value-derived price target	$40.00

Notes on assumptions:

[1] Adult post-operative pain patients - primarily U.S. and European markets
(Source: National Institute of Health, National Institute for Neurological Diseases and Stroke)

[2] Patients being prescribed medication for severe or intractable post-surgical pain
(Source: Aegis Capital Corp. estimates)

[3] Peak market share - blended; factoring in competition from intravenous dexmedetomidine generics and opioid painkillers

[4] Revenue/year/prescription - projected $30 for Dex-IN and $15 for Dex-SL ($55 per vial for Dex-IV); 3% annual price increases

[5] Peak sales - treatment revenue/year x treated patients x peak market share

[6] Launch in late 2017 for Dex-IN / mid- to late 2019 for Dex-SL

[7] Patent expiry starting in 2030; Hatch-Waxman extensions may provide up to an additional five years of protection

[8] Probability of success - Precedex approved for sedation; Dex-IN has positive Phase 2 data; starting Phase 2b studies

[9] Cash flow fully taxed at 40% following launch; no significant net operating loss carry-forwards assumed

Source: Company reports; Aegis Capital Corp. estimates

Since Recro Pharma has built up an extremely modest accumulated deficit of only $23 million since inception in late 2007, we believe that it is unlikely for the company to be able to offset taxes to any significant extent. While Recro is likely to remain cash flow-negative for the foreseeable future and therefore could accumulate additional net losses in the coming years, we have chosen to utilize a 35% corporate tax rate and apply this to all future cash flows obtained from Dex-IN and Dex-SL. In addition, we are taking account of the fact that Recro's milestone obligations to Orion Pharma are likely to be extremely minor prior to product filing and approval, and that Recro is obligated to pay Orion royalties on net sales of its products if and when these reach the market.

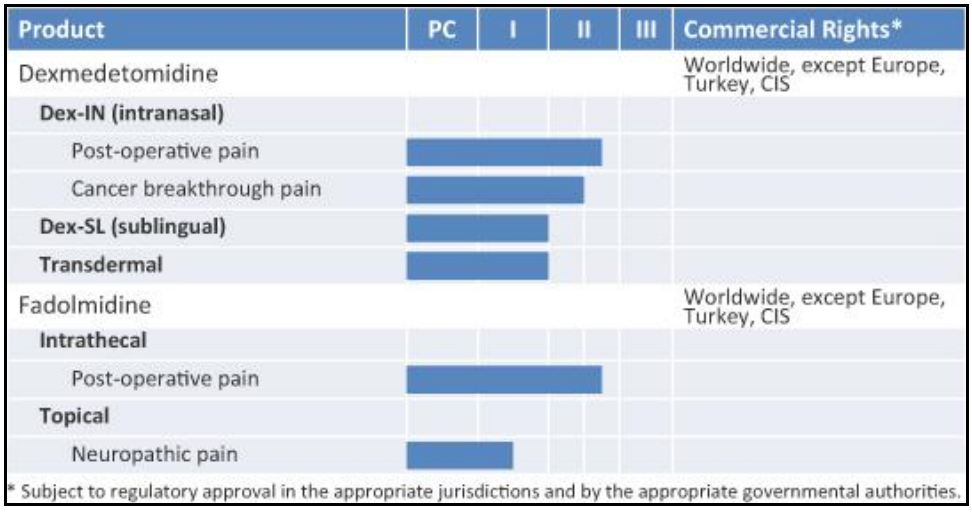
Company Overview

Recro Pharma is an emerging specialty pharmaceuticals firm developing an intranasal formulation of dexmedetomidine for post-operative pain management. The firm was founded in Pennsylvania and incorporated in the State of Delaware in November 2007. Recro Pharma shares several principals with Malvern Consulting Group, Inc. (MCG), a consulting firm focused on accelerating the development of healthcare projects and providing both strategic and advisory services to emerging healthcare-focused firms. The company rents laboratory and office space from MCG as well.

The figure below showcases Recro Pharma's development pipeline. The firm is currently in the process of advancing two drug candidates through proof-of-concept clinical studies. Both agents were originally discovered in the laboratories of Orion Pharma, a Finland-based specialty pharmaceuticals firm. The first, dexmedetomidine, is an agonist of the alpha-2 (α2) adrenergic receptor or adrenoreceptor. This receptor mediates signaling of neurotransmitters such as the catecholamines norepinephrine (noradrenaline) and epinephrine (adrenaline) in both the central and peripheral nervous systems. Dexmedetomidine has been approved in various countries, including the U.S., in an intravenous formulation for use as a sedative and anesthetic. In the U.S., it has been commercialized under the trade name Precedex by Hospira, a large specialty pharmaceuticals firm focusing primarily on the marketing of injectable drugs that are typically deployed in the hospital setting. Outside the U.S., principally in European markets, the intravenous form of the drug is sold by Orion under the trade name Dexdor. Recro is seeking to develop both intranasal (Dex-IN) and sublingual (Dex-SL) formulations of dexmedetomidine globally, excluding Europe, Turkey and countries of the Commonwealth of Independent States (CIS) including Russia. The target indications include post-operative pain as well as breakthrough cancer pain.

Recro's second drug candidate, fadolmidine, is a novel alpha-2 (α2) adrenoreceptor agonist as well. The company is seeking to develop this as an intrathecal (spine-targeted) formulation to treat post-operative pain. In our view, this pipeline has several distinct advantages – it is risk-mitigated, because the compounds in question act via a well-validated mechanism and were originally discovered by a credible company; it is capital-efficient, because clinical trials in the target indications can be performed at a low cost with a short timeline; and it possesses the potential for market expansion because of the ability to leverage a drug like dexmedetomidine across multiple additional areas.

Figure 1: Development Pipeline



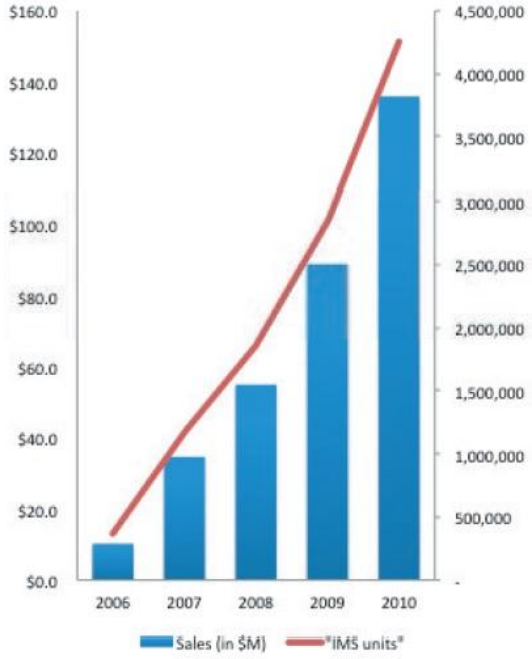
Source: Recro Pharma, Inc.

Orion, headquartered in Espoo, Finland, has a lengthy track record of innovation in the drug design and development arena. Founded in 1917, Orion sells a broad portfolio of human prescription medicines totaling roughly 300 different products. Many of these are generics, but Orion also develops novel drugs. The firm has a lengthy track record of success on this front, particularly with the Parkinson's medications Stalevo (levodopa / carbidopa + entacapone) and Comtan (entacapone), the heart failure agent Simdax (levosimendan), and the sedative agents Dexdor and Precedex.

As part of the transaction with Orion, Recro is entitled to the reimbursement of nearly half of its total R&D spending on a given dex formulation once Phase 3 development has been completed, if and only if Orion wishes to commercialize that formulation in its own territories. We consider this another positive component of the Recro Pharma investment thesis, emphasizing just how advantageous the relationship between Orion and Recro is from a business development perspective. Orion only recently received approval in many of its territories – accordingly, it has significant incentive to commercialize the drug there given the minimum of 10 years of exclusivity from which to benefit with any effective dex formulation. We believe that the back end-loaded licensing agreements between Orion and Recro on both dex and fado allow Recro to pursue drug development in as risk-mitigated and cost-effective a manner as possible, while capturing a high degree of upside potential for investors and potential licensees or acquirers in the future.

In the hands of Hospira, Precedex developed into a rapidly-growing and profitable drug. The product exhibited solid uptake among anesthesiologists and pain physicians in the hospital setting, and enabled Hospira to build an infrastructure in these markets. The sales ramp of Precedex is shown in the graph below. We note that the markets that Recro Pharma is targeting should represent significantly greater potential for growth, since Recro's dex formulations would be usable in both the post-operative setting within the hospital context – in-patient – as well as when the patients leave the hospital – outpatient – creating a much larger commercial opportunity. Even in the restricted context of hospital use, it can be seen from the chart below that Precedex achieved a high number of annual prescriptions and became a roughly $150 million-a-year drug.

Figure 2: Intravenous Dexmedetomidine (Precedex®) Sales Ramp

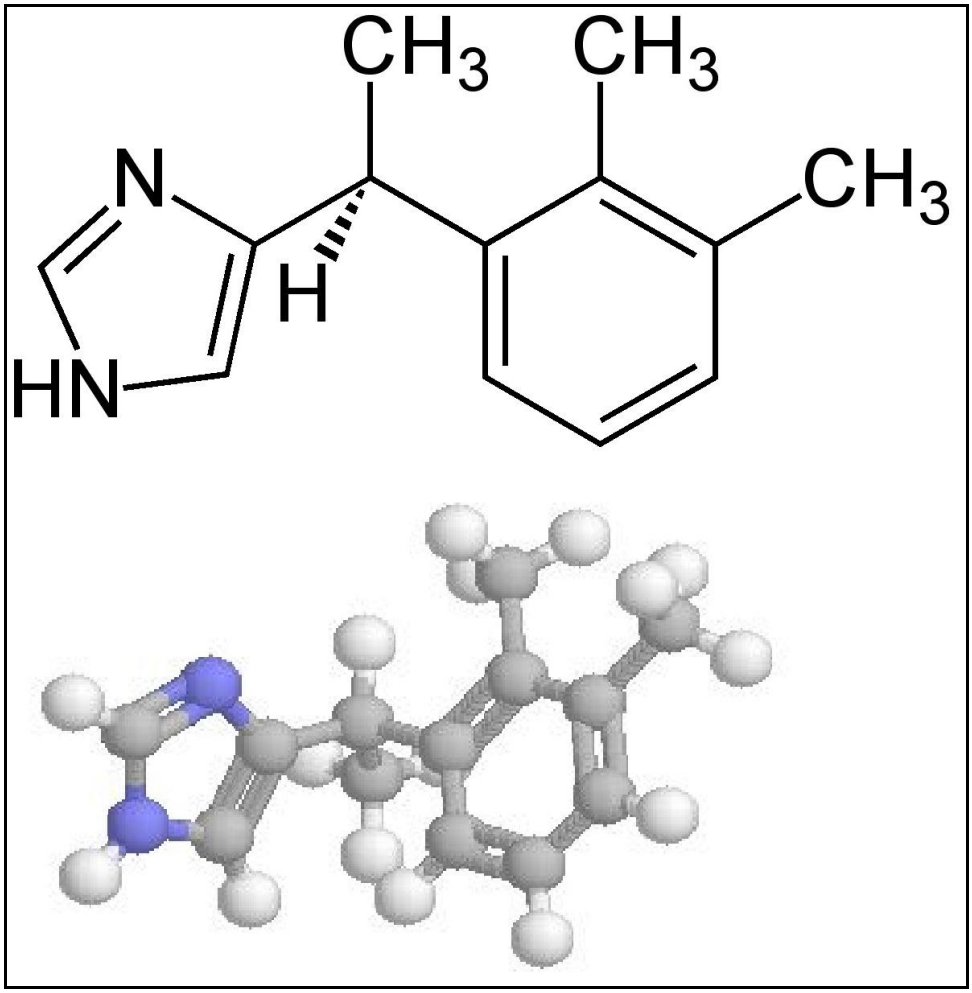


Source: IMS Health

Dexmedetomidine Overview

Dexmedetomidine (dex) is an injectable alpha-2 (α_2) adrenergic agonist, sold 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. It is the S-enantiomer of medetomidine, deployed in veterinary medicine. Dexmedetomidine hydrochloride is also used in dogs and cats. Its chemical structure is depicted below in line and 3D format.

Figure 3: Dexmedetomidine Chemical Structure



Source: Company reports, Recro Pharma, Inc.

Originally indicated for sedation of critically ill or injured patients in an intensive care unit setting, dex's usage has also recently expanded to include non-intubated patient requiring sedation for surgery or procedures short-term. Dex is also useful as an adjunct for sedation and general anesthesia in the setting of certain operations and invasive medical procedures, such as colonoscopy. There are no absolute contraindications to the use of the drug. However, its usefulness is limited since that it cannot be administered via bolus, due to concerns about peripheral α_2 receptor stimulation that can induce side effects such as hypotension (low blood pressure) and bradycardia (slowed heart rate). The drug is also expensive vs. generic medications such as propofol, fentanyl and midazolam, which have similar efficacy. We note that, as discussed in greater detail later in this report, Precedex – originally approved in 1999 – could face generic competition in coming months as composition-of-matter protection expired in January 2014.

Dex is roughly as effective as midazolam for sedation, but shortened the time to extubation. It was associated with less delirium, tachycardia and hypotension, but more bradycardia[1]. It also seemed to be superior to lorazepam for ventilated patients in the intensive care unit. Compared to midazolam, dexmedetomidine is superior due to reduced intensive care costs, due primarily to a decrease in the length of the intensive care unit stay as well as reduced mechanical ventilation. Dexmedetomidine has sedative, analgesic, sympatholytic, and anxiolytic effects that blunt many of the cardiovascular responses in the peri-operative period. It reduces the requirements for volatile anesthetics, sedatives and analgesics without causing significant respiratory depression. Dexmedetomidine may be useful for the treatment of the deleterious cardiovascular effects of acute cocaine intoxication and overdose. It may also offer a new paradigm in the pharmacologic treatment of symptoms of distress (intractable pain, agitation or delirium) at the end of life. Recently, an investigator-initiated IND was approved by the FDA to examine the use of dexmedetomidine in treating cancer patients at the end of life who are suffering from intractable pain, agitation or delirium.

Precedex and any generic equivalents are continuous IV infusions that, owing to a large difference in half-life (60-90 minutes for the intravenous form vs. 2.17 hours as an intranasal formulation at 50µg vs. 3.25 hours as a sublingual formulation), would not appear to have significant overlap with a 100µl intranasal formulation designed to be administered every four to six hours in the post-operative setting, especially after leaving the hospital. Recro is seeking to develop intranasal dexmedetomidine (Dex-IN) for the treatment of post-operative pain in an outpatient setting, such that patients receive the first dose of dex following surgery at the hospital, and self-administer subsequent doses for five to seven days at home at an estimated frequency of about every four to six hours. Dex has unique advantages in that it possesses both analgesic (pain-relieving) and anxiolytic (anxiety-reducing) qualities. Recro is pursuing a section 505(b)(2) regulatory strategy for Dex-IN, which allows the company to cross-reference existing safety data from the regulatory dossiers of Precedex and Dexdor. Physicians are already very familiar with dex, given the hundreds of thousands of patients' worth of commercial experience with the drug, which we believe will drive rapid adoption if Recro Pharma's planned clinical trials achieve success. In addition, IV dex represents a dosage level that is about ten times higher than that planned for intranasal administration, so safety is unlikely to be considered a major risk. Following potential FDA approval of Dex-IN for post-operative pain, Recro may pursue the approval of Dex-IN for cancer breakthrough pain, along with approval of sublingual dex (or Dex-SL) for clinical applications wherein the slower onset of action from sublingual administration is sufficient.

No other alpha-2 agonist compounds are currently in active clinical development for post-operative pain relief. These drugs are non-narcotic and non-scheduled products. They work by blocking the release of neurotransmitters, thus impeding transmission of sympathetic nerve impulses, providing the dual effect of sedation and analgesia. Even at high doses, α_2 agonists elicit analgesic, sedative, and anxiolytic effects without causing respiratory depression. Common side effects include bradycardia, hypotension, dizziness and somnolence. 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 for use in combination with opioids for the treatment of severe pain in opioid-refractory cancer patients. Dex is highly selective for the alpha-2 receptor compared to clonidine, with an alpha-2 to alpha-1 ratio of 1,600:1, or approximately eight times that of clonidine, which may enable dex to have enhanced analgesic effects vs. clonidine with a substantially lower likelihood of hypertension. Moreover, Dex-IN is more convenient than the epidural dosage form of Duraclon; accordingly, we believe that Dex-IN could easily compete with Duraclon.

[1] Riker *et al.*, Journal of the American Medical Association 301 (5): 489–499 (2009)

Marketed Pain Management Drugs

The global market for analgesics is forecast to reach $34.6 billion by 2015 and exceed $40 billion by 2018. Key factors driving market growth include graying population, surging number of surgical procedures, and increasing number of cancer and AIDS patients. Other factors propelling market growth include increasing popularity of the therapeutic benefits of effective pain treatment.

In our view, the pain therapeutics market, despite recent product enhancements, is yet to reach its zenith. With treatment of pain increasingly becoming multidisciplinary, pain clinics are being established that offer both conventional as well as alternative treatment modalities. Analgesics are drugs offering relief from pain. The analgesics market is one of the largest segments of the healthcare industry. The global economic turmoil that adversely impacted almost every industry had relatively minimal impact on the analgesics market. This market is mainly driven by increasing popularity of the therapeutic benefits of effective pain treatment, including reductions in healing and recovery time. Additionally, a rapidly growing geriatric population in the Western world creates a lucrative opportunity for products such as analgesics. Sports medicine is another growth area in which analgesics are typically employed.

The U.S. represents the largest market worldwide. An aging population represents the key growth driver for the U.S. chronic and acute pain management therapies market. The opioid and non-opioid pain management pharmaceuticals market holds immense potential due to significant unmet medical requirements in the pain treatment segment of the U.S. therapeutics market. Europe, the other principal market, is set to witness an upsurge in sales, aided by new product introductions. An increase in life expectancy, better treatment and increasing consumer awareness are likely to propel future growth. The Asia-Pacific region is projected to be the fastest growing regional market for analgesics, with a CAGR of more than 4% from 2007 to 2015. Within this geography, opioid-based analgesic therapy is slated to grow by roughly 8% – 10% per year.

Opioid Analgesics

The market for opioid analgesics (e.g., morphine, codeine, hydrocodone, hydromorphone, oxycodone, etc.) was reportedly worth $8.4 billion across the seven major markets in 2007. Growth has continued at a CAGR of 4% and is expected to grow at this rate through to 2018, at which time the market is expected to be worth in excess of $12 billion. This is all the more remarkable, considering longstanding market pressures including price competition, generic availability, negative stigma, and the FDA's imposition of risk mitigation and evaluation strategies (REMS) programs, in particular, on widely-used narcotic painkillers.

One drug development concept central to the opioid class is reformulation. The development of new combination therapies and delivery forms is a relatively inexpensive development process thereby presenting accessible strategies to mid- and small sized drug delivery and development companies. The attractiveness of the class is amplified by the large patient base and comparatively low market entry barriers. Reformulation of established opioids offers a useful means of treating breakthrough pain (by developing formulation with a fast onset of action) or chronic pain (by developing extended-release formulations). OxyContin, Duragesic, Kadian, Avinza and Opana are all examples of extended-release reformulations of opioids.

The current emphasis in reformulation of opioid drugs is on reducing abuse potential, frequently through the incorporation of naltrexone, an opioid receptor antagonist. The launch of several oxycodone-based controlled-release opioid drugs with anti-abuse

potential has gradually begun to erode OxyContin's market share. Despite this, it is unlikely that any individual anti-abuse opioid brands would attain blockbuster revenue levels. This reflects unclear demand from frontline stakeholders such as prescribers and patients, and the flood of brands set to enter the market. Moreover, the development of anti-abuse opioids appears to be a U.S.-specific trend, as the broad-based abuse of prescription OxyContin is primarily considered an issue in the U.S. Overall, the long-acting opioid analgesic drug market is expected to grow to roughly $7 billion in 2018 across major markets.

Reformulations enabling rapid onset of analgesia have, like extended-release formulation, also gained significant attention. In particular, rapid-acting agents have been developed in order to satisfy the demand for improved treatment of breakthrough pain. Actiq and Fentora are fentanyl formulations with trans-mucosal and buccal routes of action respectively. Choices open to physician and patient are likely to grow, as dissolvable and spray formulations advance through the pipeline. Another recently approved agent is Onsolis, a buccal disk-based fentanyl product. Unlike the anti-abuse long-acting opioids, short- and rapid-acting opioids are being developed across all three major markets (U.S., Europe and Japan). Teva's product Fentora (originally developed by Cephalon) remains among the leading brands in the U.S., however experienced firms such as Meda (Onsolis, buccal fentanyl) and Nycomed (Instanyl, intranasal fentanyl) have created substantial competition for Teva in what is becoming an increasingly fragmented European market.

Watson Pharmaceuticals, Impax Laboratories and Teva Pharmaceutical Industries have historically been the main purveyors of generic opioid drugs; several others also look to launch generics of these drugs because the substitutability is simple to achieve if similar extended-release performance can be shown. In our view, the hunt for abuse-resistant versions of opioid painkillers is likely to continue; among the most advanced candidates are drugs like Remoxy. The Remoxy approach is the formulation of oxycodone in a gelatinized capsule that dissolves into a sticky gel when crushed, rendering the result impossible to insufflate. Pain Therapeutics developed this drug in combination with DURECT Corp., which specializes in such drug delivery solutions. Although Remoxy, which is licensed to Pfizer, has suffered several regulatory setbacks, Pfizer and Pain Therapeutics appear to have remained committed to its commercialization. The current timeline indicates potential market entry in mid- to late 2016.

Injectable Acetaminophen

We note that several other companies have recently developed novel painkiller agents as well. In addition to products like Onsolis, the buccal fentanyl disk approved in 2009, agents like Ofirmev, an intravenous (IV) version of acetaminophen, have also appeared on the scene. Ofirmev, which secured US regulatory approval in 2010, was initially marketed by the specialty pharmaceuticals firm Cadence Pharmaceuticals, which was subsequently acquired by Mallinckrodt in early 2014. Its antipyretic action also makes it useful for fever reduction in patients requiring emergency intervention. The drug has generated millions of dollars in revenues under its European brand name Perfalgan.

Post-operative pain management illustrates the need for drugs like Ofirmev and dexmedetomidine. Current treatments are not adequately controlling post-operative pains, resulting in unwarranted complications following otherwise successful and safe surgeries. Uncontrolled post-operative pain, in addition to the side effects of the analgesics used, especially, the narcotics, impede the patients' recovery and ability to return to their activities of daily living, such as walking, eating, sleeping, socializing, and working. These pursuits are necessary for expediting and enhancing the patients' healing processes and expediting their recovery. Slower recovery lengthens patients' hospital stays, and therefore can add dramatically to the cost of healthcare.

The two classes of analgesics available for injectable use in the U.S. are opioids and non-steroidal anti-inflammatory drugs (NSAIDs) which have side effects that limit their indications. The intravenous opioids – morphine, fentanyl, hydromorphone, meperidine, sufentanil, and alfentanil – cause nausea, vomiting, constipation, urinary retention, itchiness, chest wall rigidity, cognitive impairment, seizures and, potential respiratory depression, which can be life-threatening. The critical need for adjunctive non-opioid intravenous analgesics that allow for lower doses of opioids led to the choice of NSAID products as the most probable solution, as they do not cause respiratory depression or impair gastrointestinal motility. In the U.S., injectable Toradol (ketorolac tromethamine) and Caldolor (ibuprofen) – NSAID drugs - were approved. Unfortunately, these drugs could not address the unmet need entirely, as both inhibit platelet aggregation, which could cause bleeding. These NSAIDS are also associated with cardiovascular adverse events and renal toxicity. They are not indicated for use in children.

Cadence's Ofirmev has advantages over the other marketed injectable drugs. First, it is approved in children. Second, it does not cause bleeding; accordingly, we expect it to be warmly received by surgeons and emergency room physicians. In addition to the clinical trial data confirming the safety of Ofirmev, the safety of acetaminophen has been established through decades of use of its oral and suppository formulations and eight years of IV formulation use. Liver toxicity is recognized as a dose-dependent adverse effect and liver failure is rare to occur when acetaminophen is given at the recommended dosage. Also, there is an effective acetaminophen antidote known as N-acetylcysteine (NAC) for use in case of toxicity, thus improving the safety profile of Ofirmev. The short duration of exposure also reduces the likelihood of side effects. Multiple clinical studies demonstrated that when given alone and in combination with opioids, the drug was safe and successful in reducing use of morphine and other opioids. In other trials with Ofirmev, the data showed that the average peak plasma concentration of acetaminophen was briefly higher for Ofirmev than for the same dose of oral acetaminophen. However, Ofirmev proved not to accumulate over multiple doses after 12 hours. Urinary metabolites with potential to interact with the liver were not meaningfully different for Ofirmev than with oral acetaminophen at 12- and 24-hour measurements. Acetaminophen has become the market leader among injectable analgesics, with sales representing >20% of all injectable analgesic units, and an estimated 45% market share of all injectable analgesic dollar sales.

Statistical and other evidence from studies of the U.S. and EU markets appear to indicate that the U.S. market is potentially larger than the European market with respect to potential unit market share and pricing. Restrictions on drug pricing in many European countries has kept the cost of injectable acetaminophen substantially lower than in countries where pricing controls are not in force. In some individual European countries, for example, the Scandinavian countries, which have less restrictive pricing controls, the price of the drug was over thrice as high as the price in price-restricting countries.

The longer-acting forms of opioid drugs are typically simply extended- or controlled-release forms of existing opioid agents. Firms specializing in such drugs include Endo Pharmaceuticals with its Opana ER franchise, as well as Purdue Pharma with OxyContin (perhaps the world's most well-known opioid painkiller for chronic pain relief) and King Pharmaceuticals with agents such as Avinza, approved in 2002, and Embeda, originally approved in August 2009, which is an abuse-resistant form of chronic morphine originally developed by Alpharma. Embeda comprises a co-formulation of morphine sulfate around a naltrexone hydrochloride core – if the pill is crushed by an addict hoping to snort the morphine, the naltrexone core dissolves and the naltrexone mixes with the morphine. Since naltrexone is a selective antagonist of the receptor that morphine targets, the mixture of naltrexone and morphine cannot create a high within the addict's system. The naltrexone core is designed not to perturb absorption when ingested.

Pain Area Valuation Benchmark Transactions

Pain relief remains a significant unmet need, and even incremental improvements can, if clinically meaningful, result in blockbuster potential. Agents to treat pain can still be developed quickly through short clinical trials with easily measurable endpoints.

Pfizer / King Pharmaceuticals

The King Pharmaceuticals acquisition was widely considered to be Pfizer's most aggressive move in the pain medication sector. Known primarily for its tamper-resistant formulations of opioid analgesics, King expanded Pfizer's portfolio in the pain category, adding Embeda, Avinza and the Flector Patch to Pfizer's Lyrica and Celebrex products. In our view, the King acquisition was another step Pfizer is making to cushion the blow from the expiration of patent protection on Lipitor, a statin agent that was once Pfizer's bestselling drug. Embeda (morphine sulfate and naltrexone hydrochloride) was approved in August 2009, and came to King through an acquisition of Alpharma, the source of King's animal health business and its Flector Patch, an NSAID patch for acute pain. King also brought Avinza (morphine sulfate extended-release capsules) to Pfizer, another reformulated pain drug. A separate oxycodone reformulation, Acurox (oxycodone HCl/niacin), which was rejected by an FDA panel in April 2010, was finally approved in June 2011 and is currently being sold under the name Oxecta. Pfizer and one of King Pharmaceuticals' erstwhile partners, Pain Therapeutics, are still pursuing the development of Remoxy (extended-release oxycodone), with additional clinical development requirements imposed by the FDA likely to delay formal approval until at least mid-2015. Pfizer was probably also motivated to make the King purchase after hitting a snag with one of its experimental products for pain – tanezumab – after some patients in clinical trials over the summer experienced a worsening of their condition after taking the drug. In our view, the downfall of tanezumab and the Lipitor patent expiration together combined to catalyze the acquisition of King by Pfizer.

Mallinckrodt / Cadence Pharmaceuticals

When Mallinckrodt was spun out of Covidien plc in 2013, enthusiasm was decidedly absent as the company was primarily viewed as a purveyor of low-margin generic drugs. However, Mallinckrodt wasted little time in trying to move aggressively into specialty drug markets with higher margins, taking over Cadence Pharmaceuticals at a 26% premium to the then-market price, valuing the company at $1.3 billion. Cadence's only marketed product, the intravenous formulation of acetaminophen known as Ofirmev, had roughly $111 million in sales in 2013. While widely considered a unique niche drug, Ofirmev had never attracted the attention of pain market-focused investors in a manner equivalent to that of Pacira Pharmaceuticals' Exparel and Cadence was often cited as an example of a "one-trick pony." Nevertheless, the fact that Mallinckrodt was willing to pay a high price for Cadence despite its possession of only one drug – which was only approved in late 2010 – demonstrates that emerging niche pain drug companies continue to be viewed as attractive targets by more established companies.

Recent Initial Public Offerings

Several successful IPOs of pain firms have occurred recently, most notably: Pacira Pharmaceuticals in February 2011, raising $42 million with a post-money valuation of <$300 million, now trading at ~$3 billion; Cara Therapeutics in January 2014, raising $55 million with a post-money valuation of ~$300 million; and Egalet Corp. in February 2014, raising roughly $58 million with a market cap of $175 million. In our view, these valuations underscore the comparative attractiveness of Recro Pharma, which trades at a market cap of just over $50 million with an enterprise value of roughly $20 million.

Adrenoreceptor Agonist Drugs

The table overleaf lists various approved adrenoreceptor agonist drugs that have been developed for use in the pain and neuropsychiatry markets. In our view, the usage of these agents demonstrates how validated the adrenoreceptor agonist mechanism of action has become from a clinical perspective. Clonidine, marketed under the trade names Catapres and Duraclon, was initially the sole α_2-agonist available for human use. Even though clonidine originally only had approval to treat hypertension, anesthesiologists began to use it as an anesthetic adjunct to facilitate the management of their patients. Clonidine has been employed to provide increased perioperative cardiovascular and sympathoadrenal stability as well as sedation and analgesia[2]. In 1999, dexmedetomidine, a novel selective and specific α_2-agonist, was granted marketing authorization in the U.S. for the post-operative sedation of intensive care patients[3] and was subsequently commercialized under the name Precedex in the U.S. and Dexdor in Europe.

The molecular pharmacology underlying the mechanism of action of α_2-agonists is extremely well-established. The sedative action of the α_2-agonists has been pinpointed to the locus coeruleus, the predominant noradrenergic nucleus in the brain stem[4]. More specifically, the mechanism of the sedative action of α_2-agonists has been attributed to changes in transmembrane ion conductance and hyperpolarization of excitable neural cells. This distinct mechanism of action from general anesthetics – for example, benzodiazepines such as cinolazepam, midazolam, or lorazepam – may prove particularly useful in the clinical setting. Indeed, the feasibility of dexmedetomidine in the treatment of post-operative patients requiring mechanical ventilation in the ICU has recently been assessed[5]. These patients were successfully sedated and calm but could still be awakened while connected to the ventilator. In addition, the patients did not experience respiratory depression and when weaned from the ventilator, the dosing of dexmedetomidine used for sedation did not need to be altered. The α_2-agonists can thus induce analgesia by acting at three different sites: in brain / brain stem, spinal cord and in peripheral tissues.

The α_2-adrenergic and opioid systems have common effector mechanisms in the locus coeruleus. In the spinal cord, the analgesic action of α_2-agonists is likely related to activation of the descending medullospinal noradrenergic pathways or to the reduction of spinal sympathetic outflow at presynaptic ganglionic sites. There is also significant interaction between opioids and α_2-agonists at the spinal cord level.

Epidural administration of clonidine has been widely investigated, and indeed epidural clonidine has been granted marketing authorization in the U.S. for the treatment of intractable cancer pain in opioid-tolerant patients with Orphan Drug status. Alternative routes of administration such as intrathecal administration are presently being investigated for utilization of approved and experimental α_2-agonists in analgesia. The pharmacological profile of α_2-agonists shows many beneficial facets that can be exploited by the anesthesiologists. These include both sedation and analgesia.

We note also that compounds acting through the α_2 adrenoreceptor pathway have been deployed for a significant period of time in veterinary health applications. Agents such as Rompun (xylazine), Domitor (medetomidine), and Dormosedan (detomidine) – the last two being close relatives of dexmedetomidine – have been used in both small and large animal analgesia. Dormosedan is used only in horses, while Rompun and Domitor are targeted towards other non-human mammals including dogs and cats.

[2] Kamibayashi and Maze. Anesthesiology 93: 1345-1349 (2000)
[3] Bhana *et al.*, Drugs 59:> 263-268 (2000)
[4] Correa-Sales *et al.*, Anesthesiology 76: 948-952 (1992)
[5] Venn *et al.*, Anesthesia 54: 1136-1142 (1999)

Table 3: Adrenoreceptor Agonist Drugs

Drug Name	Generic Name	Sponsor	Mechanism of Action	Target Population	Clinical Indication	Major Side Effects
Catapres	clonidine	Boehringer Ingelheim	Selective alpha-2 (α_2) agonist	Adults	Hypertension	Dizziness / somnolence / hypotension
Duraclon	clonidine	Mylan	Central α_2 / imidazoline agonist	Adults	Sedation / anesthesia	Dizziness / somnolence / hypotension
Precedex	dexmedetomidine	Hospira	Selective α_2 agonist	Adults and children	Sedation / anesthesia	Dizziness / somnolence / hypotension
Rompun	xylazine	Bayer AG	Selective α_2 agonist	Non-human mammals	Sedation / anesthesia	Hypotension / somnolence / anemia
Aldomet	methyldopa	Teva	Selective α_2 agonist	Adults	Hypertension	Bradycardia / anemia / dizziness / dry mouth
Wytensin	guanabenz	Eon Labs (now Novartis)	Selective α_2 agonist	Adults	Hypertension	Dizziness / headache / dry mouth
Ismelin	guanethidine	Novartis	Peripheral α_2 agonist	Adults	Hypertension	Hypotension / diarrhea / sexual dysfunction
Intuniv	guanfacine	Shire Pharmaceuticals	Selective α_2 agonist	Adults and children	ADHD	Constipation / dizziness / fatigue
Zanaflex	tizanidine	Elan Corporation	Central α_2 agonist	Adults	Spasticity	Hypotension / liver damage

Source: Company Reports; EvaluatePharma; ADIS R&D Insight; IMS Health

Dexmedetomidine Clinical Data

One of the key aspects of the Recro Pharma story is the substantial clinical database on the company's lead drug candidate, dexmedetomidine. Thus far, Recro completed eight trials on its own, 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 relief. Although Dex-IN showed efficacy in chronic pain, Recro decided to advance the drug in the post-operative pain setting (five to seven days following surgery), as it would be much more costly and time-consuming to develop Dex-IN for chronic pain. The table below shows the principal clinical proof-of-concept studies that Recro has completed with both intranasal and sub-lingual formulations of dexmedetomidine.

Table 4: Recro Pharma Dexmedetomidine Completed Trials

Trial	Form	Design	Outcome
REC-11-010	Dex-IN	Chronic lower back pain POC study (n=24)	Statistically significant pain relief within 30 minutes demonstrated in placebo controlled trial – single use device
REC-09-003	Dex-SL	Chronic lower back pain POC study (n=21)	Statistically significant reduction in pain intensity demonstrated in placebo controlled trial
REC-11-008	Dex-IN	Multi-dose PK study (n=12)	Safety & tolerability of IN dosage form

Source: Recro Pharma, Inc.

We note that Recro could always revisit the use of Dex-IN for chronic pain at some point in the future, although we do not currently factor this into our valuation of the company. One of the key reasons for the elongated development timeline in chronic pain is the fact that the FDA is likely to require carcinogenicity studies and chronic pain studies before granting a chronic pain label, vs. modest GLP toxicology studies and short-term pivotal efficacy and safety studies to secure approval in the post-operative pain setting. As such, Recro intends to initiate a Phase 2b trial of Dex-IN for post-operative pain in bunionectomy, with the aim of reporting results by the end of 2014. While the initial commercial use of Dex-IN would be limited to post-operative pain, Recro plans to eventually expand this into cancer breakthrough pain and chronic pain. The company also intends to pursue the development of Dex-SL, either following achievement of clinical success with Dex-IN or upon approval of the intranasal form.

Clinical Development Plan

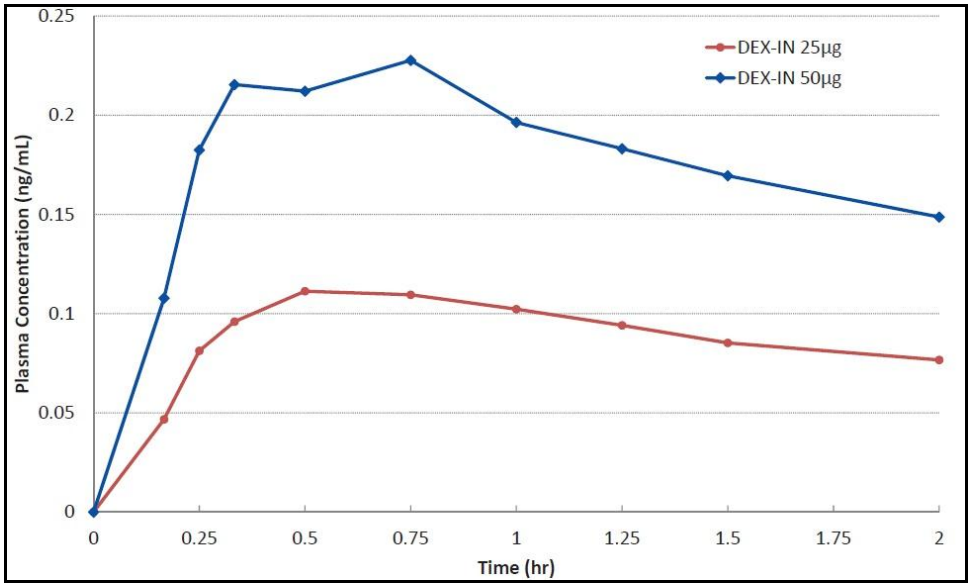
Recro plans to initiate a randomized, double-blinded Phase 2b trial of Dex-IN in roughly 150-200 patients, following bunionectomy surgery. This trial is intended to assess the efficacy of Dex-IN to control moderate-to-severe post-operative pain over 48 to 72 hours vs. placebo, with the primary endpoint being summed pain intensity difference (SPID) scores over 48 hours after surgery. Missing data is scheduled to be treated using the last observation carried forward (LOCF) method. Dex-IN is to be taken by patients every four to six hours as needed for at least 48 hours. The trial will also assess the tolerability and safety of Dex-IN, including blood pressure and sedation observations. All future trials are slated to track solely patient-reported adverse events (AEs) and not on solicitation of them, with the more favorable safety profile being reported in the absence of solicitation. This trial should last roughly six months, with top-line results expected in late 2014. We expect the start of enrollment in the coming weeks.

Assuming positive data from the Phase 2b trial, Recro plans to conduct two Phase 3 trials with Dex-IN in post-operative pain, one in intra-abdominal surgery and the other in orthopedic surgery. Each of these pivotal trials should take 6-9 months to complete and enroll approximately 200 – 250 patients, with data anticipated in either late 2015 or early 2016. In addition, Recro is slated to conduct preclinical animal toxicology studies and additional human safety clinical trials as per FDA request. Assuming positive efficacy and safety results from Phase 3 trials and other trials, Recro intends to submit an NDA via the 505(b)(2) pathway shortly thereafter, with FDA approval expected one year from filing. Accordingly, we anticipate approval of Dex-IN somewhere in the mid-2017 time frame, with market launch expected late in 2017 or early in 2018.

Phase 1b Proof-of-Concept Clinical Data

Recro Pharma conducted 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 (roughly 50% washed out after opioids and 50% post-therapy with NSAIDs). Patients received a single dose of either placebo, Dex-IN 25µg, or Dex-IN 50µg, and were allowed to cross over to any arm of the study. The efficacy endpoints were pain intensity, measured at various times up to six 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, at which point these subjects immediately received drug or placebo. The data from this study are shown below.

Figure 4: Dex-IN Phase 1b Chronic Lower Back Pain Clinical Data

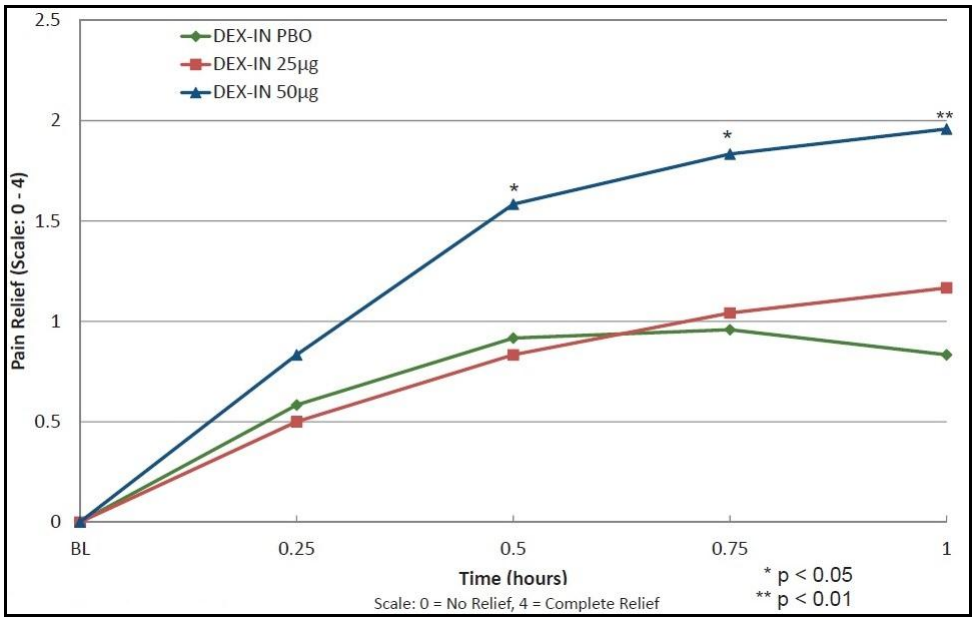


Source: Recro Pharma, Inc.

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

The figure below depicts the pain impact seen in this Phase 1b study. The onset of pain relief was rapid and sustained, with statistically significant separation from placebo at the last three time points. In our view, this represents evidence of a strong analgesic effect, particularly considering the fact that the study was so small and there were so few subjects per arm. Accordingly, we believe that this study represents an important component of the evidence Recro has gathered in favor of the Dex-IN formulation.

Figure 5: Dex-IN Phase 1b Statistically Significant Pain Relief Data



Source: Recro Pharma, Inc.

Recro management have made the point that this data compares favorably in terms of time to onset of pain relief vs. clinical data obtained with various other pain medications, including the sublingual sufentanil NanoTab. In clinical data obtained using this product at 15µg and 10µg doses in patients who had undergone major abdominal surgery, no evidence of pain relief was seen up to an hour after dosing, and significant separation from placebo only occurred after two to three hours. Dex-IN achieved pain scores similar to sublingual sufentanil among patients who had undergone knee replacement surgery[6]. We note that Dex-IN would likely be preferred vs. a drug like sufentanil for treatment of post-operative pain because, unlike sufentanil, it does not cause respiratory depression and also has documented anxiolytic activity[7]. In our view, this shows that Dex-IN has competitive and clinically meaningful efficacy with a rapid onset of action.

We note that Dex-IN was well-tolerated over the course of this Phase 1b trial. Patients were asked every 15 minutes if they were feeling any side effects, which tends to increase the frequency of adverse events (AEs). The AEs observed were generally mild and did not cause any patients to discontinue therapy with Dex-IN. The most common AEs were somnolence, dizziness, nausea, headache, and hypotension. Cases of mild sedation – which, in our view, are unsurprising for a drug like this – were reported within 60 minutes of 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. From our perspective, this is encouraging, especially considering the known discomfort associated with administration of competing products like intranasal midazolam.

[6] Singla *et al*., Regional Anesthesia and Pain Medicine 38: 131-139 (2013)
[7] Shen *et al*., Clinical Respiratory Journal 8: 100-107 (2014)

One of the most encouraging attributes of the relative product positioning for Dex-IN is the side effect profile of dexmedetomidine vs. opioid-based painkillers. As shown below, opioid analgesics have been associated with a broad array of side effects in clinical trials.

Table 5: Opioid-Based Painkiller Clinical Trial Side Effects

Event	Placebo n = 67	Tapentadol IR 50mg n = 67	Tapentadol IR 100mg n = 68	Oxycodone IR 10mg n = 67
Nausea	17.9%	46.3%	66.2%	71.6%
Dizziness	14.9%	32.8%	64.7%	56.7%
Somnolence	7.5%	28.4%	36.8%	26.9%
Vomiting	1.5%	16.4%	35.3%	38.8%
Headache	10.4%	17.9%	22.1%	20.9%
Pruritus generalized	0.0%	7.5%	13.2%	10.4%
Hyperhidrosis	1.5%	6.0%	8.8%	10.4%
Constipation	1.5%	6.0%	7.4%	17.9%
Pruritus	3.0%	7.5%	7.4%	11.9%
Feeling Hot	4.5%	7.5%	2.9%	10.4%

Source: Stegmann et al., Current Medical Research and Opinion 24: 3186-3186 (2008)

While dizziness and somnolence were recorded at substantially higher rates in the REC-11-010 Phase 1b study, we note that these were primarily observed at the 50µg dose and that both this dose and the 25µg dose were otherwise much cleaner-looking from a safety profile perspective than opioid-based painkillers, referencing available data.

Table 6: Dex-IN Phase 1b Safety Data – Adverse Events

	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: Recro Pharma, Inc.

Recro Pharma also conducted a repeat dosing study – designated REC-11-008 – that evaluated seven consecutive administrations of a 35µg dose of Dex-IN ever six hours. This trial evaluated heart rate, blood pressure and blood pressure upon standing every five minutes for two hours post-dosing. It was observed that there was a transient effect on blood pressure after initial dosing, with none of these observations being characterized by investigators as adverse events (AEs). We believe that there are significant misconceptions surrounding the cardiac safety profile of Dex-IN, and dexmedetomidine in general. Among anesthesiologists and pain physicians, the cardiac safety profile of alpha-2 adrenoreceptor agonist drugs is well-known. Furthermore, in our experience

these medical practitioners do not appear to view dexmedetomidine's cardiac safety profile as problematic. We note that, while there is a signal on various cardiac parameters, this does not seem to warrant Dex-IN's classification as problematic. Furthermore, we believe that Recro Pharma has exhaustively characterized the cardiac safety profile of its product candidate, as demonstrated through clinical evidence. The table below showcases the well-tolerated profile of Dex-IN following repeat dosing at the 35µg dosage level in the REC-11-008 study.

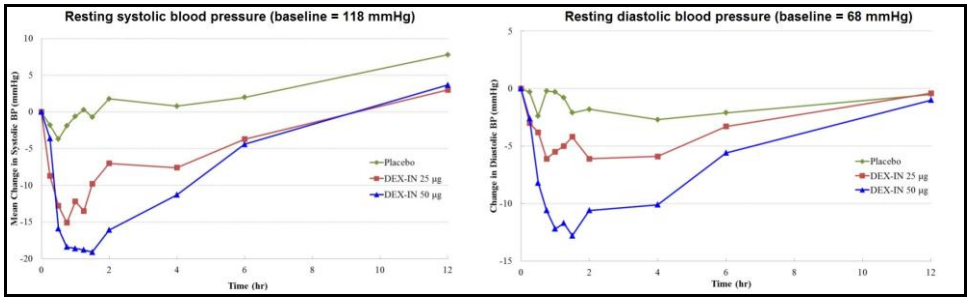
Table 7: Dex-IN Repeat Dosing Safety – Adverse Event Incidence

	Period 1 n = 12		Period 2 n = 10							
Term	D1	D2	D1	D2	D3	D4	D5	D6	D7	Total
	7am	1pm	7am	1pm	7pm	1am	7am	1pm	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: Recro Pharma, Inc.

The figure below demonstrates that the impact of Dex-IN on cardiac safety parameters – specifically, blood pressure – is clearly evident, especially at the 50µg dose, but also clearly transient in nature. In our view, the cardiac safety profile of dexmedetomidine has been shown to be manageable and we believe that Dex-IN does not show a dramatically different cardiac safety profile vs. existing formulations of the drug. The product elicits asymptomatic hypotension and bradycardia at the 50µg dose, but we do not believe that these effects are likely to be restrictive to usage as an analgesic.

Figure 6: Dex-IN Phase 1b Blood Pressure Safety Data



Source: Recro Pharma, Inc.

As mentioned previously, Recro has studied sublingual dex (Dex-SL) in the chronic pain setting. While the drug was clearly active, the firm elected to pursue the acute pain indication because it represents a more rapid clinical development timeline and a faster path to market entry. It was observed that, at the same dosage level of 50µg, Dex-IN showed a quicker onset of action and higher plasma concentration than Dex-SL, and achieved greater reduction in pain intensity than Dex-SL. Accordingly, Recro has judiciously elected to pursue clinical development of Dex-IN first, but we note that the company could always resume development of Dex-SL in chronic pain at a later point.

Principal Potential Competitor Products

In this section, we discuss several recently-launched products that we consider to be the main potential competitors to Dex-IN within the context of post-operative pain relief in the outpatient setting. These include agents that are classified as abuse-resistant opioids as well as synthetic opioids and NSAIDs that employ convenient delivery systems.

In our view, Dex-IN is likely to be competitive with these agents both from the perspective of potency as well as with respect to safety and dosing convenience. The half-life of the drug allows for non-onerous dosing every four to six hours, while – as can be observed from the clinical data Recro has generated – Dex-IN also provides rapid onset of pain relief and statistically significant analgesic impact. Furthermore, we note the added advantages of anxiolytic capability and superior safety, with absence of addictive potential, likelihood of respiratory depression and opioid-induced constipation among the chief positives for Dex-IN.

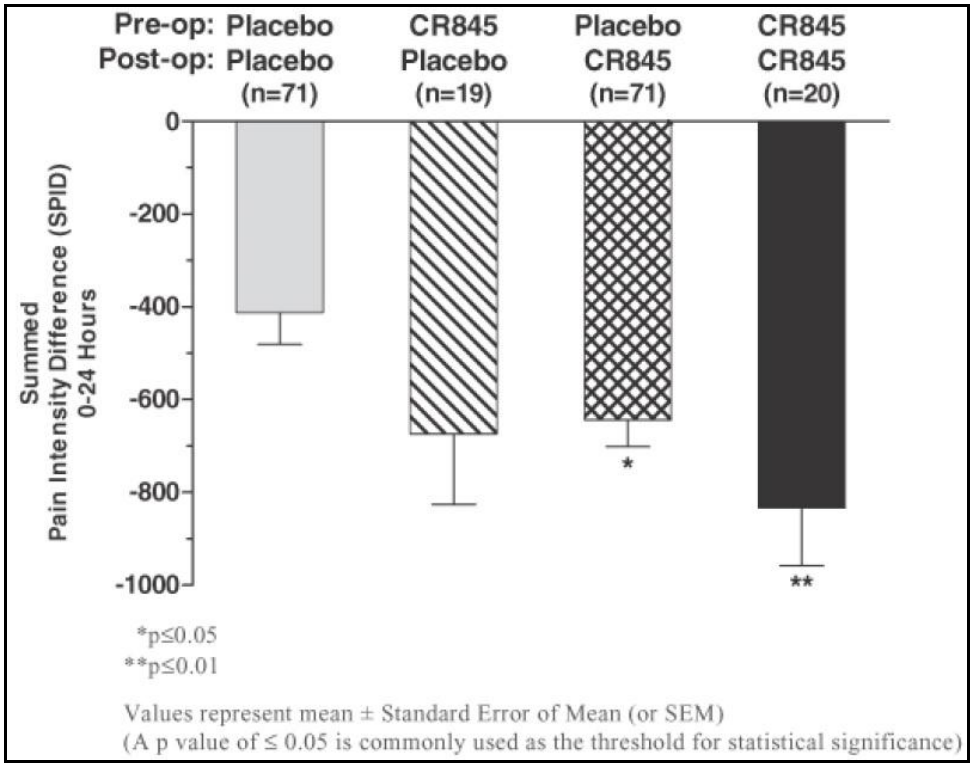
Cara Therapeutics – CR845

The subject of a recent IPO, Cara Therapeutics is a Shelton, CT-based firm focusing on the development of novel opioid- and cannabinoid-based pain medications. The firm raised $55 million by offering five million shares at $11 per share, the low end of the range, in January 2014. The firm currently has a $315 million market cap. Cara's most advanced agent is a peripheral kappa opioid (κ-opioid) receptor agonist, CR845, which is highly selective for κ-opioid receptors on peripheral pain-sensing nerves. The drug does not cross the blood-brain barrier efficiently and thus causes fewer centrally-mediated side effects than centrally-acting mu opioid (μ-opioid) receptor agonists. In animal models, CR845 was not shown to inhibit intestinal transit (ileus), induce serious respiratory depression, or elicit addiction or euphoria. An intravenous formulation (IV) of CR845 is being developed for post-operative pain, while the oral formulation of CR845 is being developed for chronic pain relief. Cara plans to initiate a Phase 3 program with IV CR845 for post-operative pain in the hospital setting in the second half of 2014. Two pivotal trials are required for approval, one in patients following soft tissue surgery and one in patients following hard tissue surgery, with the 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 vs. a product administered far less invasively, and ease of outpatient use.

The IV formulation of CR845 was assessed in three Phase 2 trials in post-operative pain, two of which were conducted in patients following laparoscopic hysterectomy surgery with the third being performed in patients following bunionectomy surgery. A proof-of-concept Phase 2a trial of IV CR845 was conducted in patients undergoing laparoscopic hysterectomy. In patients who got 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 vs. 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 at 0.04mg/kg or placebo pre-surgery, and 183 patients were re-randomized to receive IV CR845 0.04mg/kg or placebo post-surgery. Thus, there were four arms in the study, 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 statistically significant reduction in summed pain over a 24-hour period (SPID0-24) vs. placebo alone ($p<0.01$). The placebo/CR845 arm also showed a statistically significant improvement in SPID0-24 vs. the placebo arm ($p<0.05$). The CR845/placebo arm showed a numerical improvement in SPID0-24.

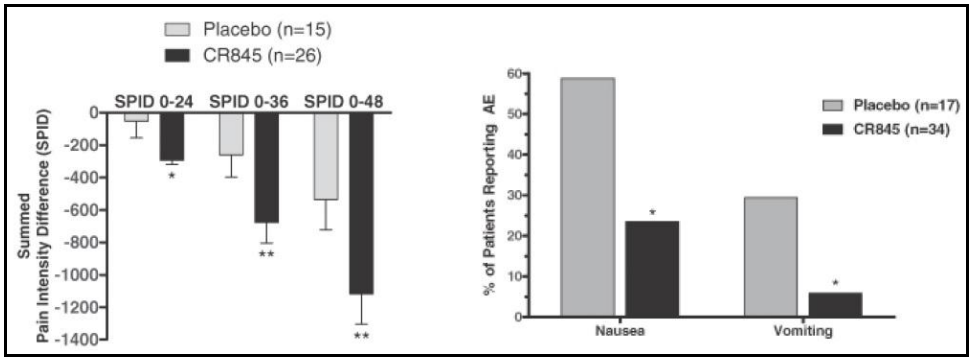
Figure 7: CR845 Phase 2b Laparoscopic Hysterectomy Trial Data



Source: Cara Therapeutics, Inc.

In a Phase 2 trial of 0.005mg/kg IV CR845, 51 bunionectomy patients were randomized 2:1 to receive an initial bolus dose of IV CR845 or placebo, and again 30 – 60 minutes later at patient request, and thereafter up to every eight hours at patient request (until hour 40) over a 48-hour dosing period. Fentanyl was allowed as rescue therapy. 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 (SPID0-24 and SPID0-48 scores). CR845 also reduced nausea and vomiting (by 60% and 80%, respectively; $p<0.05$) vs. placebo over the 48-hour treatment period.

Figure 8: CR845 Phase 2 Bunionectomy Trial Data



Source: Cara Therapeutics, Inc.

Egalet Corporation – Egalet-001

Another recent IPO, though originally founded in 1995, Egalet is actually based in Værløse, Denmark. In February 2014, the firm raised $58.4 million in net proceeds from an IPO and concurrent private placement of shares with its collaboration partner, Shionogi Ltd. 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 originally evaluated Egalet-001 in Phase 1 pharmacokinetic trials and plans to initiate in 1Q14 pivotal trials that are designed to establish the bioequivalence of Egalet-001 to MS-Contin, an approved orally-bioavailable controlled-release morphine product, with NDA submission expected in late 2014. In addition, Egalet has completed Phase 1 pharmacokinetic 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 late 2014 with NDA submission expected in early 2016.

We note that, of late, certain companies have faced difficulties in convincing the FDA and physicians alike that their abuse-resistant drugs are in fact able to evade attempts by opioid-addicted individuals to abuse them. One glaring example of this would be the Zogenix agent Zohydro ER (hydeocodone bitartrate extended-release capsules), which was approved in October 2013 but subsequently became the subject of significant controversy after it was alleged that its tamper-resistant features were ineffective. Various states have taken steps to restrict Zohydro access and Massachusetts actually attempted to ban its availability entirely. The drug contains 50mg of hydrocodone, which is considered less addictive – as well as less potent – than oxycodone.

The original painkiller that started the debate over abuse of opioid medications, the infamous OxyContin, which was initially introduced in 1996 by Purdue Pharma, contains up to 80mg of oxycodone. The main issue with abuse of opioid drugs, as mentioned previously, is the deployment of these agents in treatment of chronic pain, where it has been argued that their use is unnecessary and inappropriate. Within the context of acute pain – particularly in the hospital setting – very few would argue that opioid-based painkillers represent perhaps the most effective ways to achieve rapid and effective analgesia. However, in the chronic pain setting, the abuse potential and addictive qualities of agents such as OxyContin have necessitated the development of abuse-resistant opioids. We believe that the recent controversy over the level of abuse-resistance that these new products offer should help to position a firm like Recro even more favorably with products such as Dex-IN, Dex-SL and fadolmidine.

Sprix (Ketorolac Tromethamine)

Sprix nasal spray was approved by the FDA in 2010 for short-term (up to five days in adults) management of moderate to moderately severe pain. Sprix is currently being commercialized in the U.S. by Regency Therapeutics, which is a division of Luitpold Pharmaceuticals. Luitpold is itself a division of Daiichi Sankyo, Inc., Japan's second-largest drug maker. Although other formulations of ketorolac tromethamine – both oral and injectable – have been available for many years for short-term pain relief, intranasal ketorolac is the first and only intranasal NSAID due to an inability to formulate other NSAIDs in water-soluble form. Sprix can cause gastrointestinal side effects, primarily ulceration and perforation, bleeding, and renal complications, all common NSAID-associated risks. We believe that Dex-IN should have a significant safety advantage vs. Sprix in this regard. Furthermore, we note that Sprix has been commercialized in a sub-optimal manner, with the launch plagued by supply issues and sales rep dissatisfaction.

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 eight hours in the first trial or every six hours in the second trial for up to five days. A patient-controlled analgesia (PCA) regimen using morphine was allowed in both trials as rescue therapy. The primary efficacy endpoint was the six-hour summed pain intensity difference (SPID-6), but was later changed to SPID-24 and SPID-48 at the request of the FDA. 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 vs. 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 vs. placebo ($p=0.004$).

AcelRx – Zalviso™ (Sufentanil NanoTab PCA System)

AcelRx is a comparatively more mature IPO, which went public in February 2011. The firm raised $40 million in a relatively weak offering; the original offering size had been up to $86 million. The company currently has a market cap of $375 million. In December 2013, AcelRx and Grunenthal GmbH – a German specialty pharmaceuticals company – inked a commercial collaboration agreement covering the European Union, certain other European countries and Australia for Zalviso™, previously known as ARX-01) for potential use in pain treatment within or dispensed by a hospital, hospice, nursing home or other medically supervised setting. AcelRx received an upfront cash payment of $30 million. Furthermore, AcelRx is eligible to receive ~$220 million in additional development-, approval- and sales threshold achievement-related milestone payments. Grunenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales in the Grunenthal territory.

Zalviso™ is a drug-device combination product utilizing the opioid agonist sufentanil formulated in a proprietary sublingual tablet formulation and delivered through a pre-programmed, non-invasive proprietary delivery device. The drug was originally submitted to the FDA in September 2013, with the agency accepting the application on November 26, 2013. AcelRx currently expects FDA action in late 2014, with the possibility of launching the drug in the U.S. – assuming approval – in early 2015.

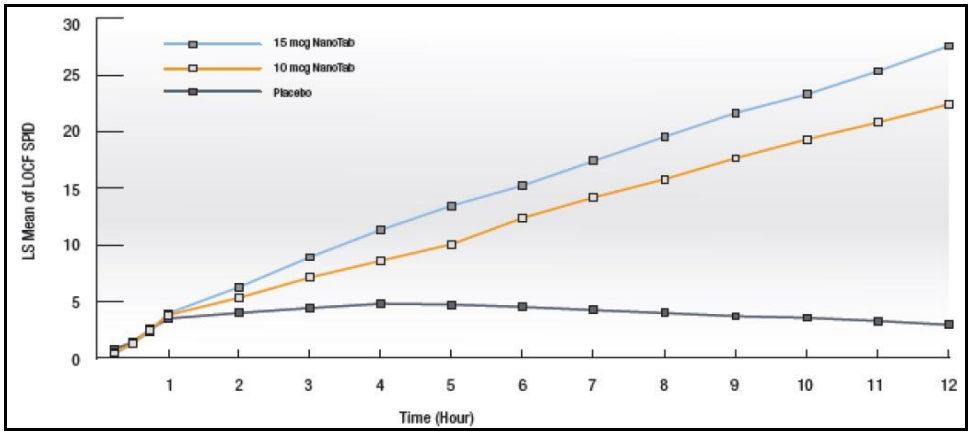
Figure 9: Zalviso™ Product Packaging / Delivery System

Source: AcelRx Pharmaceuticals, Inc.

Two Phase 3 trials of Zalviso™ at the 15µg dose, one in patients following open abdominal surgery and the other in patients following knee or hip replacement surgery, demonstrated 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.

Data from two Phase 2 trials – one in abdominal and the other in knee replacement surgery – showed that Zalviso™ significantly reduced pain intensity via 12-hour summed pain intensity difference (SPID-12). Dex-IN showed rapid separation vs. placebo on the SPID endpoint 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 a faster onset of action. In one Phase 2 trial (see figure below), 92 patients following major abdominal surgery were randomized to placebo, 10µg or 15µg doses of Zalviso™ after post-operative care unit pain stabilization. Both doses of Zalviso™ significantly reduced pain intensity vs. placebo in this study ($p<0.01$) and resulted in a lower percentage of patient dropouts due to inadequate analgesia ($p<0.001$). There were no drug-related serious adverse events (SAEs), and the most common adverse event was nausea at similar frequency in all treatment arms.

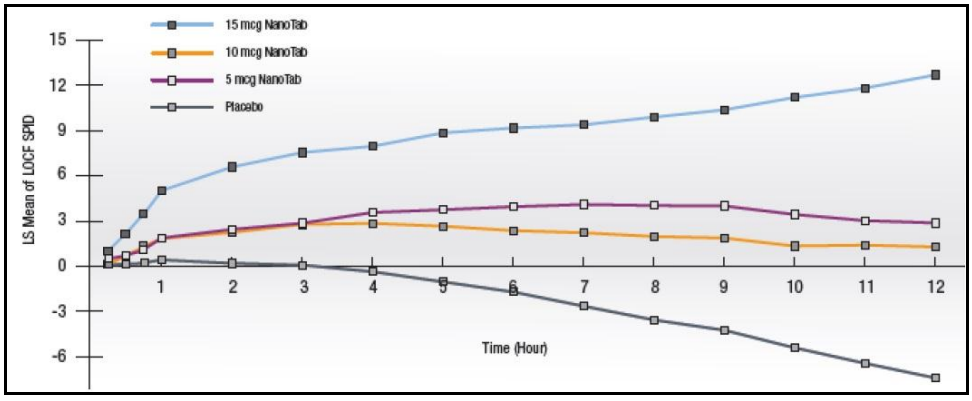
Figure 10: Zalviso™ Phase 2 Major Abdominal Surgery Trial Data



Source: AcelRx Pharmaceuticals, Inc.

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. Data from this study are shown below.

Figure 11: Zalviso™ Phase 2 Knee Replacement Surgery Trial Data



Source: AcelRx Pharmaceuticals, Inc.

In the knee replacement study, only the 15µg Zalviso™ dose significantly reduced the pain intensity compared to placebo and reported a lower percentage of patient dropouts due to inadequate analgesia vs. placebo. The safety profile of the drug was similar to that seen in the previous Phase 2 trial, with no SAEs being reported.

In our view, the relatively cumbersome delivery device and monitoring requirements for Zalviso – in addition to the relatively slow onset of action – mean that Dex-IN should be competitive against this product. We believe that, overall, the pain management field is plagued with product safety issues and inadequate product efficacy. This should create a substantial opportunity for agents such as Dex-IN and Dex-SL, as well as fadolmidine. As shown in the table below, current pain medications all carry various drawbacks.

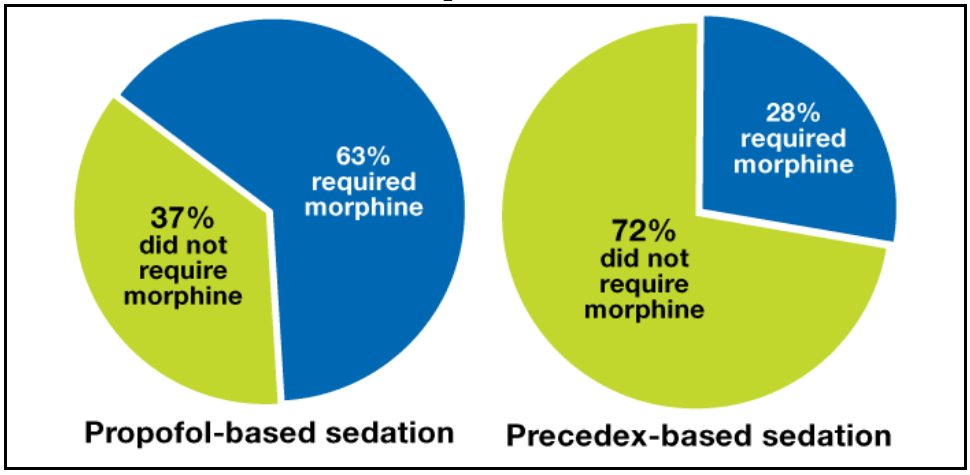
Table 8: Current Pain Relief Therapy Comparison Chart

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: Recro Pharma, Inc.

We would also advise investors to take note of the fact that dexmedetomidine has long been associated with a favorable product profile. One example of this can be illustrated in the chart below, which depicts reduced reliance on morphine when using dex for sedation purposes vs. propofol – another widely-deployed sedative agent.

Table 9: Sedation Product Competitive Profile



Source: Hospira, Inc.

Dexmedetomidine Market Model

We have modeled sales for dexmedetomidine in both intranasal and sublingual form. In its intravenous injectable formulation – Precedex®, as marketed by Hospira, Inc. – dexmedetomidine is available in a 100µg/mL concentration in a 2mL preservative-free vial. The average wholesale price is approximately $55.00 per vial. For comparison, a 5mg vial of midazolam costs approximately $5.00.

Our market model projects revenues out to 2030, the year of projected expiration of patent protection on the intranasal (Dex-IN) and sublingual (Dex-SL) formulations of dexmedetomidine. In the case of the intranasal formulation, we are projecting approval of this agent in mid-2017, based on an expected NDA filing based on the 505(b)(2) pathway projected in the first half of 2016. We expect the drug to be launched in late 2017. Based on CDC data, we estimate roughly 60 million patient visits to hospital and ambulatory centers for surgical procedures in the U.S. this year.

We expect that Dex-IN will likely be most widely used in a surgical environment, with significant use to relieve pain in the post-operative setting. Furthermore, we believe that the duration of therapy with Dex-IN is likely to be relatively short, thus translating into a price per course of therapy of roughly $30 – $35 in the U.S. We believe that this should represent an achievable price point given the current cost of intravenous Precedex®. The majority of post-operative pain care lasts for two or three days in the hospital. In Canada, Australia and other ex-U.S. markets that belong to Recro Pharma under its licensing agreement with Orion, we assume pricing at about 75% of the level projected in the U.S.

We assume that all Dex-IN and Dex-SL use will be in the hospital, growing to a peak in the 2023 / 2024 time frame in the U.S. and 2026 / 2027 ex-U.S.. The peak market penetration rate for Dex-IN is expected to be roughly 12% in the U.S. and roughly 5% ex-U.S., which we believe to be conservative considering the advantages of these agents over existing opioid-based painkillers. This translates into peak sales of $350 million in the U.S. in 2023 and roughly $56 million ex-U.S. in 2027. In the case of Dex-SL, we assume revenue of roughly $15 per patient at launch. In our view, this represents a reasonable estimate of comparable pricing to IV acetaminophen, which was initially priced at roughly $10 per vial in the U.S. We apply the same 75% discount to ex-U.S. pricing as was the case for Dex-IN. We expect Dex-SL to achieve peak market penetration rates of roughly 3.5% in both the U.S. and ex-U.S. markets. This translates into peak sales of $28 million in the U.S. in 2023 and $20 million ex-U.S. in 2027.

For all future cash flows, we have applied a blanket discount rate of 15%. Furthermore, we have assumed a relatively modest inflation rate of 3% per year, which we apply to all pricing assumptions. In the case of Dex-IR and Dex-SL, we have applied a probability of success of 85%, based on the relatively advanced status of these formulations and the thoroughly characterized safety and efficacy profile of the parent drug. This derives a risk-adjusted Net Present Value (rNPV) of approximately $740 million, to which we apply a standard corporate tax rate of 35% and marketing offset of 20% in order to derive our after-tax NPV of $390 million.

In our view, the success of other controlled-release opioid agents such as Opana CR and the prospects for broad usage of an agent with the improved safety profile of an agent such as fadolmidine indicate solid market potential for this agent in chronic pain relief. While we have not modeled sales of fadolmidine herein, we note that this agent could add a risk-adjusted NPV contribution of up to $50 million to the overall composite valuation. Although the Orion Pharma patent estate on fadolmidine expires in 2016, Hatch-Waxman extensions and New Chemical Entity (NCE) status could provide a minimum of five years of market exclusivity from the point of launch.

Table 10: Dexmedetomidine Estimated Global Sales – Post-Operative Pain Management Market Size Model

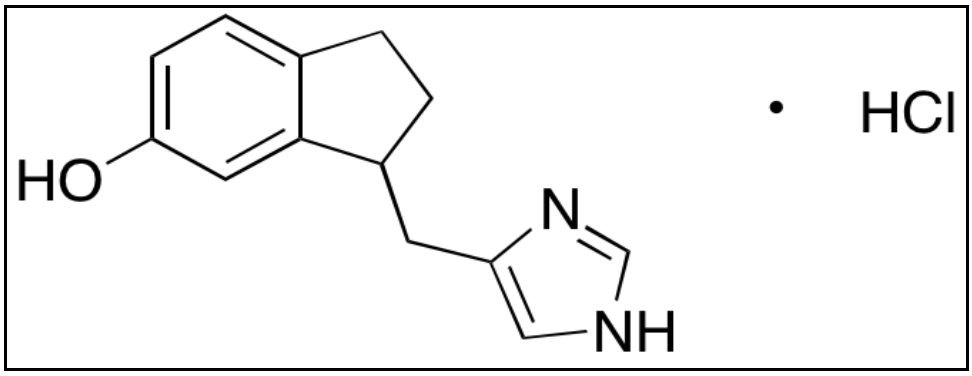
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
United States																	
Hospital in-patients	17,800,000	18,156,000	18,519,120	18,889,502	19,267,292	19,652,638	20,045,691	20,446,605	20,855,537	21,272,648	21,698,101	22,132,063	22,574,704	23,026,198	23,486,722	23,956,456	24,435,586
Hospital surgery centers	24,250,000	24,735,000	25,229,700	25,734,294	26,248,980	26,773,959	27,309,439	27,855,627	28,412,740	28,980,995	29,560,615	30,151,827	30,754,864	31,369,961	31,997,360	32,637,307	33,290,053
Ambulatory surgery centers	18,200,000	18,564,000	18,935,280	19,313,986	19,700,265	20,094,271	20,496,156	20,906,079	21,324,201	21,750,685	22,185,698	22,629,412	23,082,001	23,543,641	24,014,513	24,494,804	24,984,700
Population Growth rate	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*
Dex-IN penetration	0.0%	0.0%	0.0%	1.2%	5.8%	7.5%	8.5%	10.0%	11.2%	12.0%	11.2%	9.8%	8.3%	7.6%	6.6%	5.8%	3.2%
Dex-SL penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	1.2%	1.4%	1.8%	2.3%	2.7%	3.1%	3.4%	3.6%	3.2%	2.8%	2.0%
Number of patients receiving Dex-IN				789,008	3,771,551	4,962,402	5,743,654	6,915,547	7,877,066	8,605,742	8,195,299	7,350,332	6,375,959	5,884,746	5,251,789	4,713,635	2,620,373
Number of patients receiving Dex-SL						396,972	791,411	989,133	1,305,521	1,683,945	1,981,841	2,321,131	2,619,363	2,827,630	2,542,174	2,237,573	1,658,806
Cost of IN therapy (per treatment)				$30	$35	$36	$37	$38	$39	$41	$42	$43	$44	$46	$47	$48	$50
Cost of SL therapy (per treatment)						$15	$15	$16	$16	$17	$17	$18	$18	$19	$20	$20	$21
Dex-IN sales ($ MM)	$0.0	$0.0	$0.0	$23.7	$132.0	$178.9	$213.3	$264.5	$310.3	$349.2	$342.5	$316.4	$282.7	$268.7	$247.0	$228.4	$130.8
Dex-SL sales ($ MM)	$0.0	$0.0	$0.0	$0.0	$0.0	$6.0	$12.2	$15.7	$21.4	$28.4	$34.5	$41.6	$48.3	$53.7	$49.8	$45.1	$34.4
Canada / Australia / Other ex-U.S. areas																	
Hospital in-patients	8,000,000	8,160,000	8,323,200	8,489,664	8,659,457	8,832,646	9,009,299	9,189,485	9,373,275	9,560,741	9,751,955	9,946,994	10,145,934	10,348,853	10,555,830	10,766,947	10,982,286
Hospital surgery centers	11,000,000	11,220,000	11,444,400	11,673,288	11,906,754	12,144,889	12,387,787	12,635,542	12,888,253	13,146,018	13,408,939	13,677,117	13,950,660	14,229,673	14,514,266	14,804,552	15,100,643
Ambulatory surgery centers	6,500,000	6,630,000	6,762,600	6,897,852	7,035,809	7,176,525	7,320,056	7,466,457	7,615,786	7,768,102	7,923,464	8,081,933	8,243,572	8,408,443	8,576,612	8,748,144	8,923,107
Population Growth rate	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*
Dex-IN penetration	0.0%	0.0%	0.0%	0.3%	0.8%	1.3%	2.0%	2.4%	2.8%	3.4%	3.9%	4.4%	4.7%	5.0%	4.2%	3.7%	2.2%
Dex-SL penetration	0.0%	0.0%	0.0%	0.0%	0.3%	0.8%	1.2%	1.6%	1.9%	2.3%	2.7%	3.1%	3.5%	3.7%	2.8%	2.6%	1.8%
Number of patients receiving Dex-IN				92,325	211,074	354,410	582,226	690,360	851,211	1,046,304	1,225,699	1,395,688	1,535,207	1,654,523	1,427,676	1,264,443	783,861
Number of patients receiving Dex-SL					86,053	214,744	356,993	461,197	578,800	704,507	839,278	998,430	1,133,808	1,220,518	942,768	888,273	621,872
Cost of IN therapy (per treatment)				$25	$26	$27	$27	$28	$29	$30	$31	$32	$33	$34	$35	$36	$37
Cost of SL therapy (per treatment)					$12	$12	$13	$13	$14	$14	$14	$15	$15	$16	$16	$17	$17
Dex-IN sales ($ MM)	$0.0	$0.0	$0.0	$2.3	$5.4	$9.4	$15.9	$19.4	$24.7	$31.2	$37.7	$44.2	$50.1	$55.6	$49.4	$45.1	$28.8
Dex-SL sales ($ MM)	$0.0	$0.0	$0.0	$0.0	$1.0	$2.7	$4.5	$6.0	$7.8	$9.8	$12.0	$14.7	$17.2	$19.1	$15.2	$14.8	$10.6
Global Dex-IN & Dex-SL sales	**$0.0**	**$0.0**	**$0**	**$26**	**$138**	**$197**	**$246**	**$306**	**$364**	**$419**	**$427**	**$417**	**$398**	**$397**	**$361**	**$333**	**$205**
Royalty rate on Dex sales	**0%**	**0%**	**0%**	**10%**	**10%**	**10%**	**12%**	**15%**	**16%**	**18%**	**18%**	**18%**	**18%**	**18%**	**18%**	**18%**	**18%**
Worldwide revenue to Recro Pharma	**$0.0**	**$0.0**	**$0.0**	**$23.4**	**$124.6**	**$177.2**	**$216.4**	**$259.8**	**$305.9**	**$343.3**	**$349.9**	**$341.9**	**$326.6**	**$325.7**	**$296.3**	**$273.3**	**$167.8**

Source: Company Reports and Aegis Capital Corp. estimates

Background on Fadolmidine

In this section, we provide a brief discussion of Recro Pharma's second pipeline candidate, fadolmidine (fado)., which has been assessed in one Phase 1 study and in one Phase 2 study. Overall, 130 subjects have been given the drug. The Phase 2 study was a randomized, single-blind, controlled, dose-escalation trial, aimed at assessing the safety, tolerability and efficacy of fadolmidine when administered intrathecally with bupivacaine to induce spinal anesthesia in subjects undergoing hallux valgus surgery. Fadolmidine doses of 40, 60, 80, 100, 120, 140, 160, 180, 200, 220 and 240 µg were administered with 5mg of bupivacaine. At each dose level, six subjects were randomized to receive combination treatment, and one subject to receive only isobaric bupivacaine 10mg. In this study, fado was shown to have beneficial effects on post-operative pain. The time to first dose of rescue PCA morphine appeared prolonged with increasing fado dosages, while total morphine use in the first ten hours was reduced. Concomitantly, the subjects not only used less morphine, but they also reported less pain. All doses of the study drug appeared to delay the onset of pain whereas doses of fadolmidine >120µg also appeared to suppress pain in addition to delaying its onset. Fado was well-tolerated by subjects. There were no apparent dose-related adverse effects except for urinary incontinence and bradycardia at the highest dose studied. The incidence of nausea and vomiting was higher with fado vs. bupivacaine 10mg alone, despite the reduction in IV morphine administered. Sedation did not appear to be increased with fadolmidine. There were significant reductions in blood pressure after intrathecal fado when added to bupivacaine. These increases were dose-dependent.

Figure 12: Fadolmidine Chemical Structure



Source: Recro Pharma, Inc.

In a preclinical profiling study, fadolmidine displayed high affinity and full agonist efficacy at all three human α_2-adrenoceptor subtypes (A, B and C) in transfected Chinese hamster ovary (CHO) cells with EC_{50} values (nM) of 0.4, 4.9 and 0.5, respectively[8]. Fadolmidine also inhibited electrically evoked contractions in rat vas deferens, demonstrating the activation of rodent presynaptic α_{2D}-adrenoceptors (EC_{50} = 6.4nM). Moreover, fadolmidine was a full agonist at human α_{1A}-adrenoreceptor (EC_{50} = 22nM) and α_{1B}-adrenoreceptor (EC_{50} = 3.4nM) in human LNCaP (human prostatic adenocarcinoma) cells and transfected human embryonic kidney (HEK) cells, respectively. Fadolmidine also demonstrated potent α_2-adrenoceptor agonist activity *in vivo* by inhibiting electrically induced tachycardia in pithed rats and increasing mean arterial pressure in anesthetized rats. However, after systemic administration, fadolmidine had considerably weaker CNS-mediated effects (mydriasis and sedation) vs. dexmedetomidine, possibly due to the fact that fadolmidine exhibits limited penetration through the blood brain barrier. Fadolmidine thus appears to have potential for therapeutic use in pain management, potentially via intrathecal or topical administration.

[8] Lehtimäki *et al*., European Journal of Pharmacology 599: 65-71 (2008)

Recro Pharma Licensing Agreements

One of the principal advantages that Recro Pharma holds as an emerging specialty pharmaceuticals company is the nature of the licensing agreements that the company has inked in order to gain access to the global commercial rights for dexmedetomidine and fadolmidine, excluding Europe, the Commonwealth of Independent States (ex-Soviet republics, including Russia), and Turkey. We note that these agreements – in keeping with the kinds of licensing structures that Recro's CEO, Gerri Henwood, has employed in the past – have the principal characteristics of low to non-existent milestone payment obligations until after drug approval as well as relatively low royalty rates on net sales of commercial products. Recro does not, however, have the right to receive royalties on sales of dex or fado products by Orion or its potential future sub-licensees in the territories that Orion retains. In our view, the nature of these licensing agreements enables Recro to conduct clinical development in a cost-effective manner without having the requirement to pay onerous milestones to Orion upon clinical success – thus, the agreements are heavily back end-loaded and therefore substantially more risk-mitigated, as Recro must only start paying milestones after dex and / or fado are approved.

Dexmedetomidine Licensing Agreement

In August 2008, Recro Pharma entered into its first license agreement with Orion, which was for non-injectable dex formulations. Under the terms of this agreement, Recro was granted an exclusive license to commercialize these products globally outside Europe, the CIS and Turkey, as noted above. Recro also entered into a Supply Agreement with Orion, pursuant to which Orion is obligated to supply Recro with development quantities of dex at no cost. Upon approval, Orion will supply commercial quantities of bulk active pharmaceutical ingredient (API) dex for commercialization.

Recro is slated to pay milestone payments to Orion of up to €20.5 million ($27.9 million at the euro-dollar exchange rate of €1 = $1.36) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. Recro is also obligated to pay Orion royalty payments on net sales of its products, which are to be paid at varying percentages depending upon the achievement of certain pre-specified sales levels. Recro also has an API agreement with Orion for the supply of the drug, which we believe provides fair and arm's-length pricing for the purchase of the API that is produced in compliance with cGMP regulations and which addresses certain circumstances related to the provision of qualified manufacturing facilities or alternatives. In our view, while the royalty rate to be paid to Orion could reach double-digit levels, these payment obligations are again back end-loaded and only provide for Orion to receive substantial profits if the various dex formulations are commercially successful. Thus, we believe that the structure of this licensing agreement positions Recro well whether the firm stays independent or becomes the subject of pursuit from potential acquirers.

Fadolmidine Licensing Agreement

In July 2010, Recro inked an agreement with Orion on fadolmidine. Under the terms of this arrangement, Recro were granted an exclusive license to commercialize products globally, excluding Europe, the CIS and Turkey as noted above. In exchange, Recro is slated to pay milestones to Orion of up to €12.2 million ($16.6 million at the exchange rate of €1 = $1.36) based solely on regulatory filings and approval and on commercialized net sales levels. Royalties are to be paid at varying percentages based on net sale levels. Similar to the dex agreement, this deal is heavily back end-loaded, and only favors Orion once fadolmidine has achieved a measurable level of commercial success. Thus, we believe that the licensing deals Recro has struck demonstrate the business acumen of the firm's management team, particularly its CEO, Gerri Henwood.

Intellectual Property

The Recro Pharma intellectual property (IP) portfolio is shown below. We note that, while dexmedetomidine as a chemical entity is neither eligible for composition-of-matter protection nor New Chemical Entity (NCE) status in the U.S., the company does possess fundamental pending IP around the intranasal and sublingual formulations, which should provide protection until the 2030 time frame without patent term extensions. Much of the firm's most valuable IP is still pending, however, as shown in the table below. The patent protection on the intravenous formulation of dexmedetomidine expired in January 2014 and there are currently four Abbreviated New Drug Application (ANDA) filers of record, although no generic versions of Precedex® have been launched as of yet. The known ANDA filers are Akorn, Caraco, Mylan and Sandoz.

Table 11: Recro Pharma Patent Portfolio

Patent Number	Title	Issue Date	Expiry Date	Country	Description
6,716,867	Use of dexmedetomidine for Intensive Care Unit sedation	3/31/1999	10/1/2019	United States	Final valid use patent for dexmedetomidine
6,313,311	Imidazole derivatives with affinity for alpha-2 receptors	10/2/1996	10/2/2016	United States	Composition-of-matter protection for fadolmidine
12/781,628	Methods of treating pain without significant sedation via oral / transmucosal analgesic compositions	NA	2030 (predicted)	United States	Method-of-use protection for oral transmucosal dex administration
13/520,959	Methods of treating pain by skin-based application of active analgesic compositions	NA	2030 (predicted)	United States	Method-of-use protection for transdermal dex administration
13/711,407	Methods of treating or preventing pain via intranasal administration of active analgesic compositions	NA	2030 (predicted)	United States	Method-of-use protection for intranasal dex formulation

Source: Company reports

Generic Dexmedetomidine Status

We believe that it is worth commenting at length upon the current status of generic versions of intravenously-administered dexmedetomidine, which was commercialized under the brand name Precedex® by Hospira. Precedex® is currently approved in three strengths and for two indications: (1) sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting; and (2) sedation of non-intubated patients prior to and/or during surgical and other procedures. FDA's Orange Book currently lists two patents for the 100µg (base)/mL packaged in 200µg(base)/2mL single-dose vials strength at issue: (1) U.S. Patent No. 4,910,214 ("the '214 patent"), which expired on July 15, 2013, but was subject to a period of pediatric exclusivity that expired on January 15, 2014; and (2) U.S. Patent No. 6,716,867 ("the '867 patent"), which expires on March 31, 2019, but is subject to a period of pediatric exclusivity that expires on October 1, 2019. The '214 patent is listed in the Orange Book as a drug product (formulation), drug substance (active ingredient), and method-of-use patent. The '867 patent is listed in the Orange Book as a method-of-use patent with a "U-1472" patent use code, which is defined in an Orange Book addendum as: "Intensive Care Unit Sedation, Including Sedation Of Non-Intubated Patients Prior To And / Or During Surgical And Other Procedures."

The Precedex® Orange Book patent listings were not always as they currently appear. Information on another patent – U.S. Patent No. 5,344,840 ("the '840 patent") – was listed for the drug in November 2008. The '840 patent, which expired on September 6, 2011 (well before the FDA's March 12, 2013 grant of pediatric exclusivity), was listed as a method-of-use patent with a "U-912" patent use code, which is defined as: "Sedation Of Non-Intubated Patients Prior To And / Or During Surgical And Other Procedures." In addition, the '867 patent was, until earlier this month, listed with a "U-572" patent use code defined as "Intensive Care Unit Sedation." We note, therefore, that there was a change to the patent use code for the '867 patent. This change may be the reason why the FDA did not approve any ANDAs on January 15, 2014 for generic intravenous formulations of dexmedetomidine when pediatric exclusivity applicable to the '214

patent expired – this contains a "Section VIII" statement to omit (i.e., "carve out") from proposed labeling information protected by the '867 patent.

We have seen patent use code changes in previous situations. Indeed, in Caraco Pharmaceutical Laboratories, Ltd. vs. Novo Nordisk A/S, 132 S. Ct. 1670 (2012), the U.S. Supreme Court considered a use code change in the context of Prandin® (repaglinide) Tablets and ruled that "[a] generic manufacturer may employ the counterclaim provision [of the FDC Act] to force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using a drug". However, the FDC Act's counterclaim provision is not at issue in the case of Precedex®. In fact, that provision (at FDC Act §505(j)(5)(C)(ii)(I) for ANDAs and at FDC Act § 505(c)(3)(D)(ii)(I) for 505(b)(2) applications) is inapplicable in the case of a "Section VIII" carve-out, because the statute requires "a patent infringement action against the [ANDA] applicant."

Given the unique situation relative to generic competitors to Precedex®, the FDA is seeking comment on three sets of questions. The FDA's questions raise some intriguing issues, including whether an ANDA "carve-in" is permissible, and whether a patent use code change can be considered late-listed. Specifically, the FDA is soliciting comment on the following questions:

1. Does the breadth of the new use code description for the '867 patent foreclose ANDA applicants from gaining approval for any of the approved indications (or for any subset of those indications) before the '867 patent expires? For example, would it be permissible as a scientific, regulatory, and legal matter for an ANDA applicant to submit a statement under 21 U.S.C. §355(j)(2)(A)(viii) and a corresponding carve out that results in an approval for a subset of the second approved indication, i.e., an approval explicitly limited to procedures outside of an intensive care setting? In this context, is it acceptable to add new words to the approved indication to limit the indication to exclude only that portion of the indication that is covered by the use code (i.e., to exclude sedation of non-intubated patients in the ICU setting only)? If you believe a carve-out of this type is permissible, if you wish, you may submit a side-by-side of the indication section of the labeling for dexmedetomidine hydrochloride injection showing the carve-out that you believe would be acceptable.

2. Whether the fact that Hospira changed the use code information outside of the 30-day window after the patent issued means that the use code change is late-listed as to any ANDAs pending with a Section VIII statement at the time the use code was changed? See 21 C.F.R. § 314.53(c), (d). If so, would any ANDA with an existing Section VIII statement be entitled to retain that statement (and corresponding carve-out) under 21 C.F.R. § 314.94(a)(12)(vi), notwithstanding the change in use code?

3. What relevance, if any, to a determination of whether the use code change was submitted in a timely manner is the fact that Hospira previously listed the '840 patent with very similar use code information to that now listed for the '867 patent, and did not change the use code for the '867 patent until after the '840 patent expired?

Initial comments were required to be submitted to the FDA by the close of business on January 24, 2014. Commenters submitting in the initial comment period were permitted to respond to comments from other commenters, and had to submit those responses to FDA by the close of business on January 31, 2014. It is currently unclear how long after January 31, 2014 it might take the agency to render a decision and issue a formal letter. If history is any indication of future events, then the FDA's decision on the questions raised in the agency's solicitation and the FDA's decision on pending ANDAs may end up in court in the not-too-distant future. We also note that the plot thickened in February 2014, when a New Jersey federal judge vacated an order invalidating one of the patents

asserted in Hospira Inc.'s suit challenging a bid by Sandoz for approval of a generic version of Precedex®, following a settlement recently reached between the parties. The deal, struck in December 2013, permits Sandoz to launch its generic version of the sedative in December 2014.

The complaint, first filed in 2009, accuses Sandoz of violating Hospira and Orion Corp.'s jointly owned U.S. Patent No. 6,716,867 and Orion's U.S. Patent No. 4,910,214. Federal Circuit appeals by both parties have been held in abeyance pending the district court's resolution of the motion to vacate. Also, on the same day that the vacating of the patent invalidation occurred, U.S. District Judge Mary L. Cooper shot down an attempt by Caraco Pharmaceutical Laboratories Ltd. to intervene in the action, saying any decision regarding vacating the ruling would affect a Michigan federal suit that Hospira launched in November 2010 in an effort to keep a generic version of Precedex® off the market.

The memorandum opinion said the cross-motion to intervene was untimely, and that, while "it is unfortunate that plaintiffs and defendants could not settle the dispute at issue before this Court issued the May 2012 opinion ... this court sees no reason to squelch a settlement agreement reached by the parties to this action while the dispute at issue is pending at the appellate level."

Hospira and Orion launched the lawsuit in September 2009 after Sandoz filed its ANDA to the FDA seeking approval for generic Precedex®. The '867 patent, issued in 2004, is titled "Use of dexmedetomidine for ICU sedation" and expires in March 2019. Sandoz sent the plaintiffs a letter in July 2009 alerting them that it was seeking approval to market a generic version of Precedex® before the two patents expired, according to the amended complaint. The letter was accompanied by a detailed statement laying out the basis for Sandoz's opinion that the patents wouldn't be infringed by the manufacture, sale or importation of the proposed generic, which alleged that the patents were invalid.

In May 2012, Judge Cooper barred Sandoz Inc. and Sandoz Canada from making, using, selling or importing their generic drug until July 2013. She also ruled that the '867 patent was invalid as obvious. After both parties appealed to the Federal Circuit, and reached the settlement, they asked Judge Cooper to vacate parts of her ruling if the appeals court remanded the action. It did so, for the limited purpose of the district court's consideration of the parties' motion to vacate, in late December. The judge declared that Caraco, which moved to intervene in December, can still argue that the '867 patent is invalid in the Michigan suit. However, Judge Cooper also stated that the firm's argument "that the May 2012 opinion carries precedential weight ... is without merit in view of the appellate proceedings that remain pending before the Federal Circuit."

While the point at which generic versions of intravenous dexmedetomidine reach the market is of some relevance to Recro, which will likely be targeting some of the same physicians likely to use these generics with its proprietary formulations, we note that the intranasal and sublingual forms of dexmedetomidine that Recro is developing were designed to be deployed for the management of post-operative and intractable forms of pain, not primarily for the purpose of sedation. Accordingly, as we have stated elsewhere in this report, the genericization of Precedex® is unlikely to preclude commercial traction from being achieved with Dex-IN or Dex-SL. Nevertheless, we believe that it is likely to be of interest to investors when generic versions of Precedex® enter the market in the U.S., and we continue to expect the arrival of these products before the end of 2014.

Financing History

Recro Pharma has raised ~$43.9 million since inception (see below). In our view, the firm has an extremely capital-efficient operating history, having accumulated a deficit of only $23 million as of end-March 2014. Many other pharmaceutical companies expend hundreds of millions of dollars to advance a single candidate into clinical development. Recro benefits from having a very lean organizational infrastructure and a potentially accelerated route to market entry for dexmedetomidine under the 505(b)(2) pathway.

Table 12: Financing History

		Net Proceeds	Shares	Price	Notes
Private Company					
	Common Stock	$ 10	156	$ 0.06	
	Common Stock	$ -			
	Convertible Preferred	$ 4,000	2,000	$ 2.00	$1,880.037 accrued dividends outstanding at 12/31 - converts at 0.4 per preferred share
	Convertible Bridge Notes	$ 9,401			Converted at 75% of IPO price
Public Company					
	IPO	$ 30,491	4,313	$ 8.00	Includes over-allotment - exercised in full as of closing
	Secondary	$ -			
Total Amount		$ 43,902	6,468		

Source: Recro Pharma Inc.

Capital Structure

On March 12, 2014, Recro Pharma priced an IPO, in which the firm sold 3.75 million shares of common stock at a price of $8.00 per share and also granted the purchase of 562,500 shares of common stock to cover over-allotments; this was exercised in full, resulting in gross proceeds totaling $34.5 million, with net proceeds estimated at $30.3 million after deducting underwriting fees and cash offering expenses. The most recent capital structure (see table below) indicates that Recro Pharma has ~8.5 million shares outstanding and issued (fully-diluted) following the IPO. We project that the firm's current cash position should be sufficient to fund Phase 3 development of the intranasal formulation of dexmedetomidine, although more capital would be required to fund approval and potentially to enable the independent launch of intranasal dex in the U.S.

Table 13: Capital Structure

	Number of Shares	Exercise Price	Expiration Date	Total Cash
Cash, cash equivalents and marketable securities				$29,905,016
Common Stock	7,707,600			
Preferred Stock				$0
Options	334,800	$6.00	2020	$2,008,800
Options	301,026	$8.00	2019 - 2020	$2,408,208
Warrants	150,000	$12.00	3/12/2019	$1,800,000
Fully Diluted Shares	**8,493,426**			**$36,122,024**

Source: Recro Pharma, Inc.

We note that the firm converted $9.6 million worth of convertible bridge notes, originally bearing interest at 8% per annum, and $2.7 million of accrued interest into roughly 2.05 million shares of common stock at a 25% discount to the IPO price of $8.00 per share.

Financial Review and Outlook

Revenue: We do not forecast any revenue from either product sales or research activities in either 2014 or 2015. Management does not provide guidance.

Gross Margins: As a development-stage company, there are historically no costs of goods sold. We project that the gross margins on intranasal dex are likely to exceed 70% upon launch, which should enable healthy cash flow generation.

Operating Expenses: For 2014, we estimate approximately $11.5 million in operating expenses. We estimate R&D of $6.4 million in 2014, as the company advances its lead drug candidate into Phase 2b testing in the U.S. However, the R&D expense should rise substantially in 2015 to roughly $12.8 million as the two required pivotal trials of intranasal dex are initiated, ramp up enrollment and mature to yield data.

Taxes: We assume a roughly 40% corporate tax rate after all net operating loss carry-forwards are exhausted. However, in our view the firm should not have significant tax liabilities prior to 2020. At the end of 2013, Recro Pharma had relatively negligible net operating loss carry-forwards with which to offset taxes. We would expect that the firm could have as much as $50 million in net operating losses by the time intranasal dex receives approval in the U.S. for the treatment of post-operative pain. Accordingly, the effective tax rate in the initial years is likely to be negligible.

Share Count: The outstanding fully-diluted share count stands at roughly 8.5 million. The fully-diluted shares account for the conversion of roughly 0.8 million shares in the form of options and warrants. Given the company's cash position, strategic goals, and capital structure, a share repurchase program is unlikely, in our view.

EPS: We forecast diluted EPS of ($2.46) and ($2.18) for 2014 and 2015, respectively. Currently, we cannot estimate when the company is likely to achieve cash flow break-even or attain sustainable profitability. However, if the firm's lead drug candidate, intranasal dex, demonstrates statistically significant efficacy and positive safety data in the upcoming Phase 2b trial, we anticipate that Recro should be able to secure approval of the drug in mid- to late 2017 and potentially launch it before the end of that year. In our view, the drug's sales ramp should be rapid enough to potentially drive cash flow positive status at Recro Pharma in either late 2017 or early 2018.

Balance Sheet: The firm held roughly $29.9 million in cash at the end of the first quarter of 2014, following the completion of an IPO in March 2014. We anticipate that the funds raised in the IPO should cover the cost of the proposed Phase 2b trial for intranasal dex, which is slated to cost roughly $5 million, and thereafter facilitate the conduction of two pivotal trials of the drug. Following the receipt of data from its Phase 2b program, we believe that Recro Pharma may elect to raise additional capital in order to have as many strategic options available as possible (including being able to launch the drug in the U.S. independently using either a contract or in-house specialty sales force).

Cash Flow: We estimate that the firm will consume roughly $16.8 million in operating cash flows during 2014 and a further $22.1 million during 2015. We think additional funding may be required within the next 12 – 15 months to support envisaged operational activities, including the completion of the pivotal development of intranasal dex and the advancement of both sublingual dex and fadolmidine into active clinical development.

Guidance: The firm does not provide financial guidance.

Management Team

The firm's management team comprises individuals with substantial track records in the biotech and healthcare industries. The firm's CEO, Gerri Henwood, has had an extensive career in the specialty pharmaceuticals and large-cap pharmaceuticals arenas, and in our view is one of the most astute leaders we have come across.

Gerri Henwood

President & Chief Executive Officer

Ms. Henwood has served as the firm's President and CEO and as a director of the company since its inception. From 2006 to 2013, Ms. Henwood served as the President of MCG. She continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including firms that are engaged in the development and commercialization of other pharmaceutical products. She is also a consultant to SCP Vitalife, a cross-border venture capital firm that invests in Israeli and U.S.-based life science companies. Prior to this, Ms. Henwood was the President and CEO of Auxilium Pharmaceuticals, Inc., a company she founded in late 1999 and took public in August 2004 that currently has a market capitalization of over a billion dollars. Ms. Henwood was instrumental in the commercialization of the testosterone gel product Testim®, which at its peak generated hundreds of millions of dollars in sales for Auxilium. In addition, she led the negotiations that culminated in Auxilium's in-licensing of Xiaflex™, an injectable collagenase product that has been approved in both the United States and Europe for the treatment of Dupuytren's contracture, an orphan disease involving contractile collagen cord formation in the palm of the hand. Xiaflex™ was also recently approved in the U.S. for treatment of Peyronie's disease, a condition involving abnormal curvature of the penis. A true pipeline in a single product, Xiaflex™ is the cornerstone of Auxilium's future and has applicability in multiple areas, including treatment of cellulite, lipomas and frozen shoulder. In our view, Ms. Henwood's role in the licensing of Xiaflex™ and the manner in which she structured the licensing agreement demonstrate her visionary qualities as a leader in the biopharmaceutical sector. From 1985 to 1999, Ms. Henwood was the founder and CEO of IBAH, Inc., or IBAH, a contract research organization. IBAH reached a net revenue level of $150 million, as a NASDAQ traded company, before being acquired by Omnicare in 1998. Ms. Henwood began her career with Smith Kline & French, now part of GlaxoSmithKline plc, in the pharmaceutical management program. She rose through the ranks to be a brand manager, then the head of Regulatory and Medical Affairs for the U.S. business and then to the position of Group Director – Marketing in the International Pharmaceutical Division. Ms. Henwood serves on the board of directors of Alkermes plc, a global biopharmaceutical company, and two private companies. Ms. Henwood holds a B.S. in Biology from Neumann University.

Charles Garner

Chief Financial Officer / Chief Business Officer / Treasurer

Mr. Garner was appointed as the firm's CFO, Chief Business Officer and Treasurer in October 2013. From June 2011 to April 2013, Mr. Garner was an independent contractor to Inverness Advisers. In such capacity, Mr. Garner provided investment banking and financial advisory services to Recro Pharma as an independent contractor. From March 2010 to May 2011, Mr. Garner was a Director in the Merchant Banking Group of Burrill & Co., a diversified global financial services firm focused on the life sciences industry. From 2008 to May 2010, Mr. Garner was self-employed providing consulting and financial advisory services. From 1999 to 2008, Mr. Garner worked in the Healthcare Investment Banking Group of Deutsche Bank Securities. While with Deutsche Bank, Mr. Garner focused on assisting life sciences companies with financing and advisory transactions. He began his career at PricewaterhouseCoopers in its Business Assurance Group. Mr. Garner received his Bachelors of Business Administration, high distinction, with a concentration in accounting and finance from the University of Michigan.

Randall Mack
Senior Vice President of Development / Corporate Secretary
Randy Mack has served as the firm's Senior Vice President of Development and Corporate Secretary since 2008. From 2008 to 2013, Mr. Mack served as Executive Vice President, Development for MCG. He, like the company's CEO, continues to spend a small portion of his time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2005 to 2008, Mr. Mack served as Vice President, Project Management and Operations at Adolor Corp., where he oversaw the development programs in the areas of opioid-induced bowel dysfunction and pain management. For more than 15 years, he also held positions of increasing responsibilities at Auxilium, Abbott Laboratories and Harris Laboratories. In these positions he was responsible for the conduct of over 400 clinical trials, the filing of 20 Investigational New Drug applications (INDs) and four New Drug Applications (NDAs). Over the course of his career, he has authored more than 75 scientific articles, book chapters, abstracts and poster presentations in the areas of gastroenterology, urology, neuroscience and psychiatric disorders. Mr. Mack holds a B.S. in Biology and Chemistry from the University of Nebraska-Lincoln.

Donna M. Nichols, C.P.A.
Corporate Controller
Donna Nichols has been the firm's corporate controller since 2009. Since March 2009, Ms. Nichols has served as an employee of MCG. Ms. Nichols, like the firm's CEO and Corporate Secretary, continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2004 to 2009, she served as Director of Accounting at Auxilium, and from 1996 to 2003, as Director of Financial Reporting at Adolor Corp. In such prior roles, Ms. Nichols was responsible for the companies' financial reporting in compliance with Securities and Exchange Commission (SEC) guidelines and regulations. Ms. Nichols holds a B.S. from Rider University and is a Certified Public Accountant.

Diane Myers
Senior Vice President, Regulatory Affairs & Quality Assurance
Diane Myers has served as the company's Senior Vice President of Regulatory Affairs and Quality Assurance since 2008. From 2008 to 2013, Ms. Myers served as Senior Vice President of Regulatory Affairs and Quality Assurance for MCG. Like several other members of the firm's management team, Ms. Myers continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2000 to 2008, Ms. Myers served as Vice President of Regulatory Affairs and Quality at Auxilium. In addition, for more than 15 years she held positions of increasing responsibility at GlaxoSmithKline plc in the Quality Control and Quality Assurance groups within the Biopharmaceutical Research and Development Division. Ms. Myers holds a B.S. in Biology from Neumann University.

Board of Directors

The firm's Board of Directors includes several senior-level individuals with substantial expertise in the biopharmaceutical industry. In particular, several of the firm's directors have extensive expertise in the funding of life sciences companies and have directed investments in life sciences-focused venture capital for many years.

Wayne Weisman, J.D.
Chairman of the Board
Mr. Weisman has served as Chairman of the Recro Pharma Board of Directors since the inception of the company. He is a founder and managing partner of SCP Vitalife Partners and a partner of SCP Partners, which collectively hold more than $1 billion in assets under management in a series of venture capital investment funds. He has extensive experience in venture capital investing, particularly in the life sciences area, dating back to 1990. Mr. Weisman has been a partner of SCP Partners since its inception in 1996. SCP Partners is a multistage private equity manager with $830 million in assets under management in two funds. He has led SCP Partner's efforts in the life sciences area, which include investments in the U.S. and Israel. He has also led several other technology investments for SCP Partners. Mr. Weisman serves either as chairman of the board or as a director of several portfolio companies. In 1990, Mr. Weisman became vice president and a member of the board of directors of CIP Capital L.P., a Small Business Investment Company licensed by the Small Business Administration (SBA). Mr. Weisman led many of the successful life science investments made by CIP Capital. From 1987 to 1990, Mr. Weisman operated a management and financial advisory firm focusing on the reorganization and turnaround of troubled companies. He began his career in 1982 at a large Philadelphia law firm. Mr. Weisman received his B.A. from the University of Pennsylvania and his J.D. from the University of Michigan's School of Law. He is the chairman of the board of trustees of Young Scholars School, Young Scholars Frederick Douglass, and Young Scholars Kenderton, three inner-city public schools serving nearly 1,500 economically disadvantaged children. He is also a board member of the Philadelphia-Israel Chamber of Commerce and Mid-Atlantic Diamond Ventures, the venture forum of Temple University, located in Philadelphia, PA.

Alfred F. Altomari, M.B.A.
Non-Executive Director
Mr. Altomari brings over 25 years of operational and commercial pharmaceutical experience to Recro's Board. He currently serves as President and CEO and member of the Board of Directors of Agile Therapeutics, a privately-held specialty pharmaceuticals company focusing on the development of next-generation female contraceptive products. He also serves on the Board of Directors of Insmed Inc. Previously, Mr. Altomari was CEO of Barrier Therapeutics, and was a member of Barrier's Board of Directors, where he led the successful sale of Barrier to Stiefel Laboratories for $148 million in June 2008. Stiefel was subsequently acquired in 2009 for $2.9 billion by GlaxoSmithKline plc. Prior to Barrier Therapeutics, Mr. Altomari held numerous executive roles in general management, commercial operations, business development, product launch preparation, and finance with Johnson & Johnson. He received an M.B.A. from Rider University and his B.S. degree from Drexel University in Philadelphia, PA.

Gerri Henwood
Executive Director
See management biographies above.

William L. Ashton
Non-Executive Director
Mr. Ashton has been a director of the company since 2009. Since the beginning of 2013, he has served as a principal at Harrison Consulting Group, Inc., a privately-held biopharmaceutical consulting firm. From August 2009 to June 2013, Mr. Ashton was the senior vice president of external affairs reporting to the president and an assistant professor at the University of the Sciences in Philadelphia, Pennsylvania. From August 2005 to August 2009, Mr. Ashton was the founding Dean of the Mayes College of Healthcare Business and Policy. He has 28 years' experience in the biopharmaceutical industry. From 1989 to 2005, Mr. Ashton held a number of positions at Amgen Inc., a leading biotechnology company, including vice president of U.S. sales and vice president of commercial and government affairs. He currently serves on the boards of the publicly-traded biopharmaceutical firms Galena Biopharma, Inc. and Sucampo Pharmaceuticals, Inc. He is also a member of the board of the National Osteoporosis Foundation and Friends of the National Library of Medicine at the National Institutes of Health. Mr. Ashton holds a B.S. degree in education, from the California University of Pennsylvania and an M.A. in education from the University of Pittsburgh in Pittsburgh, PA.

Michael Berelowitz, M.D.
Non-Executive Director
Dr. Berelowitz brings over 30 years of clinical development and academic research experience to Recro Pharma, including 15 years of pharmaceutical development experience with Pfizer, Inc. While at Pfizer, Dr. Berelowitz was Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit. He also held various other roles at Pfizer, beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility. Prior to that, Dr. Berelowitz spent a number of years in academia. After completing his medical and specialty training at the University of Cape Town Medical School, Dr. Berelowitz held academic faculty positions at the University of Chicago – Michael Reese Hospital and the University of Cincinnati College of Medicine, and then served as Professor of Medicine, Pharmacology and Biophysics at SUNY Stony Brook School of Medicine for over a decade, where he led the Division of Endocrinology and Metabolism. Dr. Berelowitz currently serves as a biopharmaceuticals consultant, and is a member on several Boards of Directors or Scientific Advisory Boards, including the Endocrine Fellows Foundation, Metacure, Ltd. and Haptocure, Ltd. and Oramed Pharmaceuticals. Additionally, Dr. Berelowitz has also served on the Board of Directors of the American Diabetes Association, the Clinical Initiatives Committee of the Endocrine Society, and has chaired the Task Force on Research of the New York State Council on Diabetes. He has also served on several editorial boards, including the Journal of Clinical Endocrinology and Metabolism, Endocrinology, Reviews in Endocrine and Metabolic Disorders and Clinical Diabetes. Dr. Berelowitz has authored or co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders.

Winston J. Churchill, J.D.
Non-Executive Director
Mr. Churchill has been a director of Recro Pharma since 2008. Since 2007, Mr. Churchill has been a director of the corporate general partner of the common general partner of SCP Vitalife, which beneficially owns 33.2% of Recro Pharma's outstanding common stock as of March 31st, 2014. He has also served as a managing member of SCP Vitalife Management Co., LLC, which pursuant to contract provides certain management services to the common general partner of SCP Vitalife. Mr. Churchill has also served since 1993 as the President of CIP Capital Management, Inc., the general partner of CIP Capital, L.P., an SBA-licensed private equity fund. Prior to that, Mr. Churchill was a managing partner of Bradford Associates, which managed private equity funds on behalf of Bessemer Securities Corporation and Bessemer Trust Company. From 1967 to 1983,

Mr. Churchill practiced law at the Philadelphia firm of Saul Ewing, LLP, where he served as Chairman of the Banking and Financial Institutions Department, Chairman of the Finance Committee and was a member of the Executive Committee. Mr. Churchill is a director of Griffin Land & Nurseries, Inc., Innovative Solutions and Support, Inc., Cyalume Technologies Holdings, Inc., Amkor Technology, Inc. and various SCP Vitalife portfolio companies. In addition, he serves as a director on the boards of a number of charities and as a trustee of educational institutions including the Gesu School and Scholar Academies and is a Trustee Fellow of Fordham University. From 1989 to 1993, Mr. Churchill served as Chairman of the Finance Committee of the Pennsylvania Public School Employees' Retirement System. He holds a B.S. in Physics, *summa cum laude*, from Fordham University, followed by an M.A. in Economics from Oxford University – where he studied as a Rhodes Scholar – and a J.D. degree from Yale Law School.

Abraham Ludomirski, M.D.
Director
Dr. Ludomirski has been a member of the Recro Pharma Board of Directors since 2008. He is a director of the corporate general partner of the common general partner of SCP Vitalife, which collectively owns 33.2% of the outstanding common stock of Recro as of March 31st, 2014. He is a managing member of SCP Vitalife Management Co., LLC and a director of SCP Vitalife Management Company (Israel), Ltd, both of which by contract provide certain management services to the common general partner of SCP Vitalife. Previously, he founded the Vitalife Life Sciences funds in 2002 to invest in Israeli medical device technologies, and is a managing director of the limited liability company providing management services to these funds. He is also the Chairman of the board of directors of POCARED Diagnostics, Ltd., an Israeli high-tech company specializing in miniature electronics and optical and video systems, and serves on the boards of Sensible Medical Innovations Ltd., Trig Medical, Endospan Ltd., Vishay Intertechnology, Inc. and DIR Technologies. In addition to his general familiarity with corporate affairs and governance, Dr. Ludomirski's work in the high-tech venture capital and medical fields gives him a valuable perspective on investment in innovative technologies. Dr. Ludomirski earned his M.D. at the Sackler Tel-Aviv University Medical School, specializing in obstetrics and gynecology, and subsequently completed his fellowship at the University of Pennsylvania in maternal-fetal medicine.

Public Companies Mentioned in this Report:

ACADIA Pharmaceuticals (ACAD/NASDAQ)

Actavis plc (ACT/NYSE)

Ampio Pharmaceuticals (AMPE/NASDAQ – Buy)

Auxilium Pharmaceuticals (AUXL/NASDAQ)

Cara Therapeutics (CARA/NASDAQ)

DepoMed (DEPO/NASDAQ)

Durata Therapeutics (DRTX/NASDAQ)

DURECT Corporation (DRRX/NASDAQ)

Egalet Corporation (EGLT/NASDAQ)

Flexion Therapeutics (FLXN/NASDAQ)

Horizon Pharma (HZNP/NASDAQ)

GlaxoSmithKline (GSK/NYSE)

Novartis AG (NVS/NYSE)

Pain Therapeutics (PTIE/NASDAQ)

Pernix Therapeutics Holdings (PTX/NASDAQ)

Progenics Pharmaceuticals (PGNX/NASDAQ)

Revance Therapeutics (RVNC/NASDAQ)

Zogenix (ZGNX/NASDAQ)

Table 14: Recro Pharma, Inc. (REPH) – Historical Income Statements, Financial Projections

FY end December 31
$ in thousands, except per share data

			2014E					2015E				
	2012A	2013A	1QA	2QE	3QE	4QE	2014E	1QE	2QE	3QE	4QE	2015E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Royalty-based revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-
Expenses												
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	542	544	227	1,200	2,300	2,700	6,427	2,800	3,100	3,300	3,600	12,800
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative	339	546	647	1,000	1,500	1,900	5,047	2,100	2,300	2,500	2,700	9,600
Total expenses	881	1,090	874	2,200	3,800	4,600	11,474	4,900	5,400	5,800	6,300	22,400
Gain (loss) from operations	(881)	(1,090)	(874)	(2,200)	(3,800)	(4,600)	(11,474)	(4,900)	(5,400)	(5,800)	(6,300)	(22,400)
Other income/expense												
Interest income/expense	(740)	(868)	(4,273)	35	25	15	(4,198)	12	14	35	25	86
Realized loss on marketable securities												
Other income/expense	85	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	(655)	(868)	(4,273)	35	25	15	(4,198)	12	14	35	25	86
Accretion of redeemable preferred stock and deemed dividend	(413)	(440)	(1,270)	-	-	-	(1,270)	-	-	-	-	-
Loss before provision for income taxes	(1,537)	(1,958)	(6,416)	(2,165)	(3,775)	(4,585)	(16,941)	(4,888)	(5,386)	(5,765)	(6,275)	(22,314)
Provision for income taxes	-	-	-	-	-	-	-					-
Net loss/income	(1,949)	(2,398)	(6,416)	(2,165)	(3,775)	(4,585)	(16,941)	(4,888)	(5,386)	(5,765)	(6,275)	(22,314)
Net loss per share (basic)	(12.53)	(15.41)	(3.67)	(0.28)	(0.48)	(0.58)	(2.69)	(0.61)	(0.56)	(0.51)	(0.55)	(2.22)
Net loss per share (diluted)	(12.53)	(15.41)	(3.67)	(0.25)	(0.44)	(0.53)	(2.46)	(0.56)	(0.56)	(0.51)	(0.55)	(2.18)
Weighted average number of shares outstanding (basic)	156	156	1,750	7,733	7,808	7,908	6,299	8,008	9,608	11,208	11,308	10,033
Weighted average number of shares outstanding (diluted)	156	156	1,750	8,493	8,593	8,693	6,883	8,793	9,608	11,208	11,308	10,229

Source: Company Reports and Aegis Capital Corp. estimates

Table 15: Recro Pharma, Inc. (REPH) – Historical Income Statements, Long-Term Financial Projections

FY end December 31
$ in thousands, except per share data

			2014E										
	2012A	2013A	1QA	2QE	3QE	4QE	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Product revenue	-	-	-	-	-	-	-	-	-	26,000	141,000	209,000	271,000
Service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty-based revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	26,000	141,000	209,000	271,000
Expenses													
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	5,930	28,450	37,550	44,610
Research & development	542	544	227	1,200	2,300	2,700	6,427	12,800	13,500	16,000	18,000	19,200	20,000
Selling and marketing	-	-	-	-	-	-	-	-	-	13,000	25,000	38,000	48,000
General and administrative	339	546	647	1,000	1,500	1,900	5,047	9,600	12,500	14,200	18,300	22,300	26,800
Total expenses	881	1,090	874	2,200	3,800	4,600	11,474	22,400	26,000	49,130	89,750	117,050	139,410
Gain (loss) from operations	(881)	(1,090)	(874)	(2,200)	(3,800)	(4,600)	(11,474)	(22,400)	(26,000)	(23,130)	51,250	91,950	131,590
Other income/expense													
Interest income/expense	(740)	(868)	(4,273)	35	25	15	(4,198)	86	190	219	308	610	1,100
Realized loss on marketable securities													
Other income/expense	85	-	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	(655)	(868)	(4,273)	35	25	15	(4,198)	86	190	219	308	610	1,100
Accretion of redeemable preferred stock and deemed dividend	(413)	(440)	(1,270)	-	-	-	(1,270)	-	-	-	-	-	-
Loss before provision for income taxes	(1,537)	(1,958)	(6,416)	(2,165)	(3,775)	(4,585)	(16,941)	(22,314)	(25,810)	(22,911)	51,558	92,560	132,690
Provision for income taxes	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(1,949)	(2,398)	(6,416)	(2,165)	(3,775)	(4,585)	(16,941)	(22,314)	(25,810)	(22,911)	51,558	92,560	132,690
Net loss per share (basic)	(12.53)	(15.41)	(3.67)	(0.28)	(0.48)	(0.58)	(2.69)	(2.22)	(1.92)	(1.53)	3.36	5.87	8.21
Net loss per share (diluted)	(12.53)	(15.41)	(3.67)	(0.25)	(0.44)	(0.53)	(2.46)	(2.18)	(1.92)	(1.53)	3.36	5.87	8.21
Weighted average number of shares outstanding (basic)	156	156	1,750	7,733	7,808	7,908	6,299	10,033	13,433	14,958	15,358	15,758	16,158
Weighted average number of shares outstanding (diluted)	156	156	1,750	8,493	8,593	8,693	6,883	10,229	13,433	14,958	15,358	15,758	16,158

Source: Company Reports and Aegis Capital Corp. estimates

Table 16: Recro Pharma, Inc. (REPH) – Historical Balance Sheets, Financial Projections

FY end December 31
$ in thousands, except per share data

			2014E					2015E				
	12/31/12A	12/31/13A	3/31	6/30	9/30	12/31	12/31/14E	3/31	6/30	9/30	12/31	12/31/15E
Assets												
Current assets:												
Cash and cash equivalents	53	13	29,905	27,740	23,965	19,380	19,380	14,492	9,106	3,341	(2,934)	(2,934)
Marketable securities	-	-	-	-	-	-	-	-	-	-	-	-
Restricted cash	-	-	-	-	-	-	-	-	-	-	-	-
Accounts receivable	85	38	36	36	36	36	36	36	36	36	36	36
Inventories	-	-	-	-	-	-	-	-	-	-	-	-
Other assets and prepaid expenses	14	800	287	287	287	287	287	287	287	287	287	287
Total current assets	153	851	30,228	28,063	24,288	19,703	19,703	14,815	9,429	3,664	(2,611)	(2,611)
Property and equipment	1	-	-	-	-	-	-	-	-	-	-	-
Intangible assets	-	-	-	-	-	-	-	-	-	-	-	-
Restricted cash	-	-	-	-	-	-	-	-	-	-	-	-
Marketable securities												
Other assets	-	-	-	-	-	-	-	-	-	-	-	-
Total Assets	154	851	30,228	28,063	24,288	19,703	19,703	14,815	9,429	3,664	(2,611)	(2,611)
Liabilities and shareholder equity												
Current liabilities												
Accounts payable	16	434	32	32	32	32	32	32	32	32	32	32
Accrued expenses	102	590	792	792	792	792	792	792	792	792	792	792
Accrued acquisition and integration costs	-	-	-	-	-	-	-	-	-	-	-	-
Convertible notes payable	-	-	-	-	-	-	-	-	-	-	-	-
Total current liabilities	10,276	12,931	825	825	825	825	825	825	825	825	825	825
Total Liabilities	15,716	18,811	825	825	825	825	825	825	825	825	825	825
Shareholder's equity												
Common stock	2	2	77	77	77	77	77	77	81	81	81	81
Additional paid-in capital	-	-	52,434	52,434	52,434	52,434	52,434	52,434	52,430	52,430	52,430	52,430
Accumulated other comprehensive income	-	-	-	-	-	-	-	-	-	-	-	-
Deficit accumulated	(15,563)	(17,961)	(23,108)	(25,273)	(29,048)	(33,633)	(33,633)	(38,521)	(43,907)	(49,672)	(55,947)	(55,947)
Total shareholder's equity	(15,562)	(17,959)	29,403	27,238	23,463	18,878	18,878	13,990	8,604	2,839	(3,436)	(3,436)
Total liability and shareholder's equity	154	852	30,228	28,063	24,288	19,703	19,703	14,815	9,429	3,664	(2,611)	(2,611)

Source: Company Reports and Aegis Capital Corp. estimates

Table 17: Recro Pharma, Inc. (REPH) – Historical Statement of Cash Flows, Financial Projections

FY end December 31
$ in thousands, except per share data

			2014E					2015E				
	2012A	2013A	1QA	2QE	3QE	4QE	2014E	1QE	2QE	3QE	4QE	2015E
Cash flows from operating activities												
Net loss	(1,537)	(1,958)	(5,146)	(2,165)	(3,775)	(4,585)	(15,671)	(4,888)	(5,386)	(5,765)	(6,275)	(22,314)
Adjustments for:												
Stock-based compensation	(1)	-	19	25	30	40	114	50	50	50	50	200
Depreciation & amortization	2	1	-	-	-	-	-	-	-	-	-	-
Realized loss on marketable securities												
Bad debt expense												
Non-cash interest expense	740	868	4,273				4,273					-
Change in operating assets & liabilities												
Accounts receivable							-					-
Prepaid expenses	(0)	(1)	(272)				(272)					-
Other receivables	(85)	47	3				3					-
Accounts payable	(344)	226	307				307					-
Deferred revenue	-	10,159					-					-
Other liabilities	-	-					-					-
Total change in operating assets & liabilities	(430)	10,430	38	-	-	-	38	-	-	-	-	-
Cash flows from operating activities	**(1,225)**	**9,342**	**(816)**	**(2,140)**	**(3,745)**	**(4,545)**	**(11,246)**	**(4,838)**	**(5,336)**	**(5,715)**	**(6,225)**	**(22,114)**
Cash flows from investing activities												
Investment in PPE							-					-
Purchases of marketable securities							-					-
Sales of marketable securities							-					-
Maturity (purchase) of marketable securities							-					-
Cash flows from investing activities	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Cash flows from financing activities												
Proceeds from issuance of Series A redeemable convertible stock							-					-
Proceeds from initial public offering / (Offering costs)		(104)	30,533				30,533					-
Proceeds from issuance of common stock	-	-		-	-	-	-	-	36,000	-	-	36,000
Proceeds from notes payable	1,270	881	175				175					-
Cash flows from financing activities	**1,270**	**776**	**30,708**	**-**	**-**	**-**	**30,708**	**-**	**36,000**	**-**	**-**	**36,000**
Net increase/ decrease in cash and cash equivalents	**45**	**10,118**	**29,892**	**(2,140)**	**(3,745)**	**(4,545)**	**19,462**	**(4,838)**	**30,664**	**(5,715)**	**(6,225)**	**13,886**
Effect of exchange rate	-	-	-	-	-	-	-	-	-	-	-	-
Cash and cash equivalents, beginning of period	8	53	13	29,905	27,765	24,020	13	19,475	14,637	45,301	39,586	19,475
Cash and cash equivalents, end of period	53	10,171	29,905	27,765	24,020	19,475	19,475	14,637	45,301	39,586	33,361	33,361

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 18-month price target is $40.00 per share.

Valuation Methodology

Given the fact that Recro Pharma is currently unprofitable, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, we believe that the stock is worth $40.00 per share, given our estimate of a $450 million risk-adjusted net present value (rNPV) for the firm's pipeline. This assumes that the shares trade in line with the comp group average enterprise value of $450 million and that the firm has roughly 12 million shares outstanding and $37 million in cash at the end of 2015.

Risk Factors

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to complete the clinical development of its candidates and establish commercial infrastructure, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Future sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

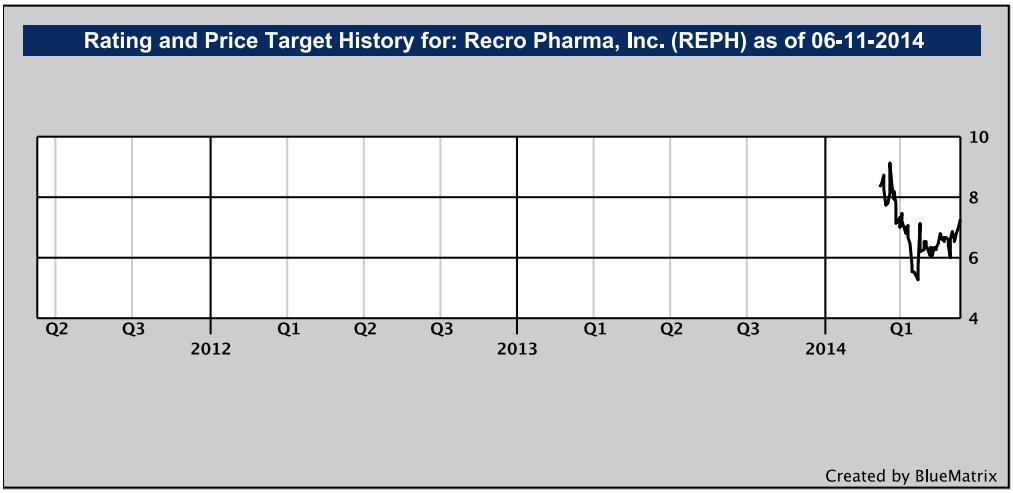
For important disclosures go to www.aegiscap.com.

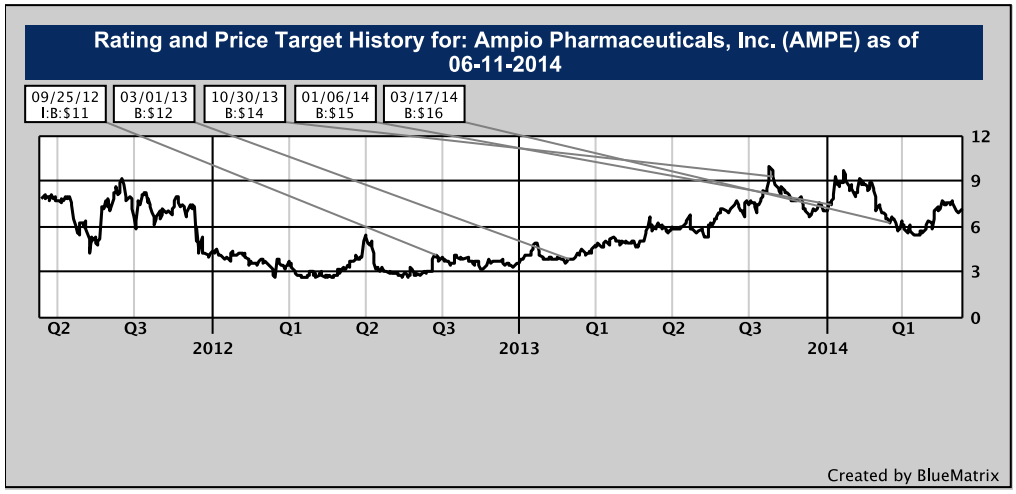
Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

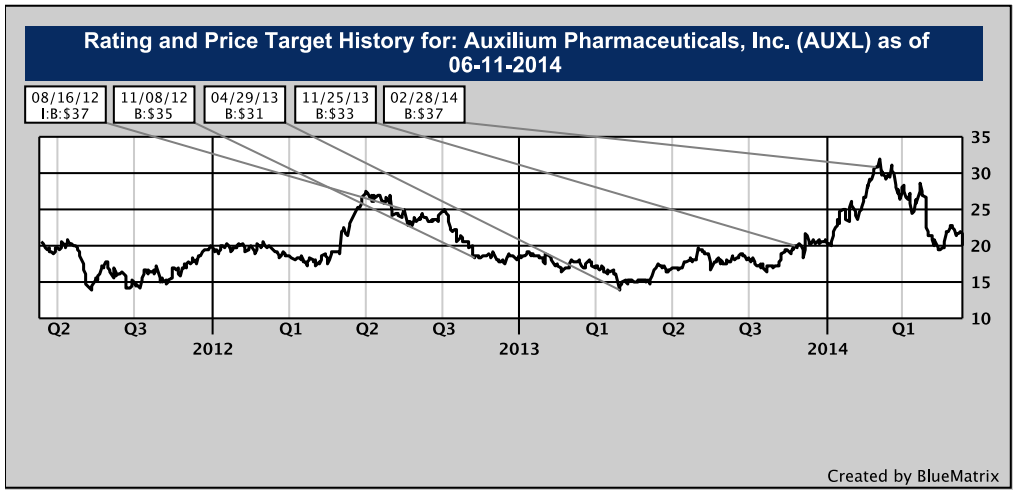
Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Recro Pharma, Inc. and Ampio Pharmaceuticals, Inc. within the past 12 months.

Aegis Capital Corp. makes a market in Recro Pharma, Inc..







Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	79.59	46.15
HOLD [HOLD]	20.41	20.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital

Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

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