Recro Pharma, Inc.
Form 424B3
July 24, 2015

Filed Pursuant to Rule 424(b)(3)

Registration Statement No. 333-201841

Prospectus Supplement No. 13

to Prospectus dated February 26, 2015

2,500,000 Shares

Common Stock

This Prospectus Supplement No. 13 supplements and amends our prospectus dated February 26, 2015 (the Prospectus), relating to the sale, from time to time, of up to 2,500,000 shares of our common stock by Aspire Capital Fund, LLC.

This prospectus supplement is being filed to include the information set forth in our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 24, 2015. This prospectus supplement should be read in conjunction with the Prospectus and any amendments or supplements thereto, which are to be delivered with this prospectus supplement, and is qualified by reference to the Prospectus, except to the extent that the information in this prospectus supplement updates or supersedes the information contained in the Prospectus, including any amendments or supplements thereto.

Our common stock trades on the NASDAQ Capital Market under the ticker symbol REPH. On July 23, 2015, the last reported sale price per share of our common stock was $15.24 per share.

Investing in our common stock involves risk. Please read carefully the section entitled Risk Factors beginning on page 8 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 13 is July 24, 2015.

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8 K

CURRENT REPORT

Pursuant to Section 13 OR 15 (d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 24, 2015

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**001-36329**	**26-1523233**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
490 Lapp Road,		**19355**

Malvern, Pennsylvania
(Address of principal executive offices) (Zip Code)
Registrant s telephone number, including area code: (484) 395 2470

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8 K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a 12 under the Exchange Act (17 CFR 240.14a 12)

¨ Pre commencement communications pursuant to Rule 14d 2(b) under the Exchange Act (17 CFR 240.14d 2(b))

¨ Pre commencement communications pursuant to Rule 13e 4(c) under the Exchange Act (17 CFR 240.13e 4(c))

Item 8.01 Other Events.

On July 24, 2015, Recro Pharma, Inc. (the Company) issued a press release announcing additional results for the Company s Phase II clinical trial of Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of acute pain in adult patients undergoing bunionectomy surgery. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On July 24, 2015, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Document
99.1	Press release of Recro Pharma, Inc., dated July 24, 2015.
99.2	Investor presentation of Recro Pharma, Inc., dated July 24, 2015.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 24, 2015

Recro Pharma, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Document
99.1	Press release of Recro Pharma, Inc., dated July 24, 2015.
99.2	Investor presentation of Recro Pharma, Inc., dated July 24, 2015.

Exhibit 99.1

Recro Pharma Announces Additional Information for Phase II Clinical Trial of Dex-IN

Additional safety and efficacy information provided

MALVERN, PA, July 24, 2015 Recro Pharma, Inc. (Nasdaq: REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post operative pain, today announced additional results from the Phase II clinical trial for Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of acute pain in adult patients undergoing bunionectomy surgery. As previously released, Dex-IN met the primary endpoint of the clinical trial in demonstrating significant pain relief compared with placebo over 48 hours (p=0.0214). The Company plans to meet with the FDA to discuss the Company s Phase III plans and determine what, if any, additional information will be required in association with the Phase III clinical program for Dex-IN.

The Phase II trial was a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Recro Pharma s proprietary intranasal formulation of dexmedetomidine, Dex-IN, in adult patients undergoing bunionectomy surgery, initiating dosing of study medication on Post Op Day 1. Patients who met the eligibility criteria were randomized to either a 50µg dose of Dex-IN or a placebo intranasal dose given every 6 hours. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 7 days after the initial dose of study medication. There was an oral opioid rescue treatment available to patients in either treatment group, if required, to provide adequate pain relief. A total of 168 patients were randomized and received study medication in the clinical trial, 84 patients in each treatment group. The key subject characteristics are listed in Table 1 below. The one discontinued subject was for a serious adverse event of hypotension.

Table 1: Summary of Key Subject Characteristics REC-14-013

Characteristic	**Placebo (N = 84)**	**DEX-IN 50 µg (N =84)**
Female, n (%)	75 (89.3)	79 (94.0)
Age, Mean	44	43.9
(range)	(46 - 70)	(46 - 69)
Discontinued Subjects, n (%)	3 (3.6)	4 (4.8)
Lack of Efficacy	3 (3.6)	3 (3.6)
Adverse Event	0	1 (1.2)
Race, n (%)		
White	56 (66.7)	59 (70.2)
Black/African American	21 (25.0)	20 (23.8)
Other	7 (8.4)	5 (6.0)
Baseline PI Score, Mean	6.7	6.4
(range)	(4 - 10)	(4 - 10)

The primary efficacy endpoint of the trial was the summed pain intensity difference over 48 hours, SPID48, utilizing the last observation carry forward analysis method. Additional efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, as well as other standard efficacy analyses. An adverse event of bradycardia was reported in 3 subjects in the Dex-IN treatment group. No patients with blood pressure decrease, hypotension nor with bradycardia required medication to treat these events. The most frequently reported adverse events reported in the Dex-IN group from the REC-14-013 trial are summarized in Table 2 below.

Table 2: Summary of Key Safety Data of Interest REC-14-013

	n (%) of Subjects	
Adverse Event	**Placebo (N = 84)**	**DEX-IN 50 µg (N =84)**
BP Decreased	3 (3.6)	22 (26.2)
Nausea	14 (16.7)	13 (15.5)
Nasal Discomfort	2 (2.4)	7 (8.3)
Headache	4 (4.8)	6 (7.1)
Vomiting	6 (7.1)	4 (4.8)
Nasal Dryness	3 (3.6)	4 (4.8)
Nasal Congestion	1 (1.2)	4 (4.8)
Nasal Obstruction	2 (2.4)	3 (3.6)
Bradycardia	0	3 (3.6)
Dizziness	1 (1.2)	3 (3.6)
Hypotension	0	3 (3.6)

All nasal related adverse events were rated as mild, except one case of nasal congestion rated as moderate.

Bunionectomy surgery generally involves an incision in the top or side of the big toe joint and the removal or realignment of soft tissue and bone. This is done to relieve pain and restore normal alignment to the joint. Bunionectomy surgery typically results in intense post operative pain. In the past, drugs that have demonstrated analgesic effectiveness following bunionectomy surgery have frequently translated that analgesic success into other post operative procedures that result in moderate to severe, acute pain.

About Recro Pharma, Inc.

Recro Pharma is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post operative pain. Recro Pharma is currently developing IV/IM meloxicam, a proprietary, Phase III-ready, long-acting preferential COX-2 inhibitor, and Dex-IN, a proprietary intranasal formulation of dexmedetomidine that has completed Phase II clinical trials, for the treatment of acute post operative pain. As Recro Pharma s product candidates are not in the opioid class of drugs, the Company believes its candidates would avoid many of the side effects associated with commonly prescribed opioid therapeutics, such as addiction, constipation and respiratory distress, while maintaining analgesic effect.

Recro Pharma also owns and operates an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Recro Pharma s expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words anticipate, believe, estimate, upcoming, plan, target , in expect and similar expressions, as they relate to Recro Pharma or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Recro Pharma as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause

Recro Pharma s performance to differ materially from those expressed in, or implied by, these forward-looking statements. Recro Pharma assumes no obligation to update any such forward-looking statements. Factors that could cause Recro Pharma s actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: results and timing of the clinical trials of IV/IM meloxicam and Dex-IN; the ability to obtain and maintain regulatory approval of IV/IM meloxicam and Dex-IN, and the labeling under any such approval; regulatory developments in the United States and foreign countries; the Company s ability to raise future financing for continued development; the performance of third-party suppliers and manufacturers; the Company s ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the successful commercialization of IV/IM meloxicam and Dex-IN; In addition, the forward-looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro Pharma s business and future results included in Recro Pharma s filings with the Securities and Exchange Commission at www.sec.gov. Recro Pharma assumes no obligation to update any such forward looking statements.

CONTACT:

Recro Pharma, Inc.

Charles T. Garner

Chief Financial Officer

(484) 395-2425

Media and Investors:

Argot Partners

Susan Kim

(212) 600-1902

susan@argotpartners.com

Relieving pain .Improving lives
Exhibit 99.2

Special Note Regarding Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements, among other things, relate to our business strategy, goals and expectations concerning our product candidates, future operations, prospects, plans and objectives of management. The words "anticipate", "believe", "could",

"estimate", "expect", "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases are used to identify forward-looking statements in this presentation. Our operations involve risks and uncertainties, including the integration of our recently acquired assets, many of which are outside our control, and any one of which, or a combination of which, could materially affect our results of operations and whether the forward-looking statements ultimately prove to be correct. These forward-looking statements should be considered together with the risks and uncertainties that may affect our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

Company Highlights

Multiple non-opioid therapeutics in advanced clinical development for acute post operative pain

IV/IM
meloxicam

Phase
III
ready
long
acting,
demonstrated efficacy in successful Ph II trials

Dex-IN
proprietary,
intranasal
therapeutic
with
recently announced positive Ph II results

Revenue and cashflow
positive manufacturing &
royalty business

Experienced management team with significant
development, regulatory and commercial experience
3

Experienced Management and Board

Gerri
Henwood

President
and

CEO
Founded Auxilium
Pharmaceuticals (AUXL,
NASDAQ) and IBAH (former NASDAQ Co.

acquired 1998); GSK

Chuck
Garner

CFO,
CBO
and
Treasurer
Over 14 years of life sciences investment
banking experience
Deutsche Bank, Burrill
& Co., Inverness Advisors; PwC

Randy
Mack

SVP,
Development
Over 20 years of clinical development
experience

Adolor,
Auxilium,
Abbott
Labs
and Harris Labs
Board of Directors
Wayne
B.
Weisman
Chairman
SCP VitaLife
Partners
Winston J. Churchill
SCP VitaLife
Partners
Gerri
Henwood

CEO
William L. Ashton
Harrison Consulting Group; frmly
Amgen
Abraham Ludomirski, M.D.

SCP VitaLife
Partners
Alfred Altomari
CEO, Agile Therapeutics
Michael Berelowitz, M.D.
Former SVP, Specialty Care Business
Unit, Pfizer
4

Recent Transformative Transaction

Acquired IV/IM meloxicam and manufacturing & royalty business from Alkermes

$50M up-front cash payment; meloxicam milestones and royalties

Warrants
issued
to
Alkermes
and
OrbiMed

Non-dilutive up-front financed by loan from OrbiMed

IV/IM
meloxicam

long
acting
preferential
COX-2
inhibitor
for
moderate
to
severe
acute
pain
ready
for
Ph
III

Widely prescribed, approved oral chronic pain therapeutic

Multiple Phase II studies successfully completed in acute pain
models

Dosing advantages over existing acute pain therapeutics, including
long action

Manufacturing, royalty and formulation business

87,000 sq. ft. facility (DEA licensed) manufactures 5 commercial
products marketed by partners

$75M in revenues and cashflow
positive (2014)
5

Positive Dex-IN Ph II Results
(REC-14-013

Post
Op
Day
1

Dosing)

Randomized, placebo
controlled
Phase
II
bunionectomy
study
(168 patients)

Randomized, placebo controlled study

50 mcg of Dex-IN or placebo every 6 hours

Primary
endpoint

SPID48
(p=0.0214)

Oral opioid rescue therapy allowed

6 patients discontinued for lack of efficacy (3 in each treatment group) and 1 patient due to serious adverse event of hypotension

Most common adverse events observed in the study were:

blood pressure decrease / hypotension

nausea (similar incidences to placebo)

nasal discomfort and headache

Adverse event of bradycardia was reported in 3 subjects in the Dex-IN treatment group
6

Clinical Stage Pipeline
Product
PC
I
II
III
Rights

Meloxicam
WW
IV formulation
Acute post operative pain
Phase III ready
IM formulation
Acute pain
Dexmedetomidine
(Dex)
WW, exc. Europe, Turkey, CIS
Dex-IN (intranasal)
Acute post operative pain
Cancer breakthrough pain
Dex-SL (sublingual)
Fadolmidine
(Fado)
WW, exc. Europe, Turkey, CIS
Intrathecal
Topical
7

Post Op Pain Market Underserved

$5.9 billion market
(1)

Predominantly opioid
use

Significant side
effects / issues
associated with
opioids

Dearth of non-opioid
drugs in development
Inpatient procedures
Total procedures (2009)
47.9M
Addressable
>25M
Ambulatory procedures
Total procedures (2006)
53.3M
Addressable
>25M
Note: Addressable includes procedures expected to
utilize pain medication.
Source: National Center for Health Statistics and
management estimates.
(1) GBI Research, 2010 sales.
8

Limited Pain Relief Options for Patients
Pain
Severity
Class
Compounds
Advantages
Disadvantages

Mild
Acetaminophen
Antipyretic properties;
Oral; no opioid AEs
Only effective for mild pain; short
acting
NSAIDs
Ketorolac,
ibuprofen, aspirin
Mild to moderate
analgesia; oral; no
opioid AEs
Bleeding risk; GI and renal
complications; short acting
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
Moderate to
Severe
Long-acting
preferential COX-2
IV/IM meloxicam
(Recro Pharma)
Long acting; fast onset,
high pain relief, and
less constipation
Bleeding risk; GI and renal
complications
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
Note: Pain severity based upon market research / physician feedback
9

IV/IM Meloxicam

IV/IM Meloxicam Overview

FDA approved, oral preferential COX-2 inhibitor used in a wide variety of indications

Proprietary long acting injectable form for moderate to severe acute pain

Incorporates Alkermes NanoCrystal technology

Phase
III
ready

multiple
Phase
II
studies
completed on IV and a Phase I on IM

Positive Ph
II hysterectomy and dental pain studies with
demonstrated efficacy

IP issued through 2022 and additional IP could
extend protection through 2030
NanoCrystal
®
is
a
registered
trademark
of
Alkermes
plc.
11

Favorable Dosing Profile
Attribute
Meloxicam
Ketorolac
Caldolor
(ibuprofen)
Ofirmev

(APAP)
Route
IV/IM
IV/IM
IV
IV
Onset of pain
relief
< 10 min
30 min
N/A
N/A
Time to peak
analgesic effect
40 min
1-2 hrs
N/A
N/A
Duration of
pain relief
18-24
hrs
4-6 hrs
4-6 hrs
4-6 hrs
Admin.
IV bolus / pre-
filled syringe
(later)
Ready to use IV
bolus (15 sec)
Dilution required,
30 min infusion
Ready to use,
15
min infusion
12

IV/IM Meloxicam Clinical Overview

Elan/ALKS conducted 5 IV and 1 IM clinical trials

Two Phase 1 IV PK & Safety trials

One Phase 1 IM PK & Safety trial

Three Phase 2 IV efficacy trials in various acute pain models

Good safety & tolerability across large dose range IV/IM

Demonstrated efficacy using various measures in multiple pain models

13

Multiple Successful IV Phase 2 Trials

Elan/ALKS have conducted 5 IV and 1 IM clinical trials
Trial
Design
Outcome
Phase II Study

N1539-02
Acute pain following dental
surgery (N = 230)
Statistically significant differences for all
doses compared to placebo were seen in
SPID24, pain relief and onset of pain relief
Phase II Study
N1539-04
Acute pain following open
abdominal hysterectomy
surgery (N = 486)
Statistically significant differences for all
doses compared to placebo were seen in
multiple efficacy analyses, including SPID24.
meloxicam 30 mg and 60 mg produced the
greatest response with no difference
between doses
Phase II Study
N1539-05
Acute pain following
laparoscopic abdominal
surgery (N =50)
Study stopped early (planned N = 250) for
business reasons. However, statistically
significant differences in SPID48 observed for
30mg QD dose despite small sample size
14

Phase II Abdominal Hysterectomy Study

Multicenter, single-dose, randomized, double-blind, placebo-
& active-controlled study in Eastern Europe

In double-blind period, single doses of:

Placebo

IV Morphine (10-15 mg)

Meloxicam 5 mg, 7.5 mg, 15 mg, 30 mg, 60 mg

After 24 hours, open-label Meloxicam was available

Standard analgesia study design

Pain Intensity assessments (SPID24 = Primary Endpoint)

Pain Relief

Rescue mediation

Time to onset
15

Robust Efficacy
(Abdominal
Hysterectomy
Trial

IV
Meloxicam)


*** p < 0.001 vs. Placebo
***
***
***
***
***
***
16
(10,000)
-
10,000
20,000
30,000
40,000
50,000
60,000
Placebo
n=64
Morphine
n=62
5 mg
n=60
7.5 mg
n=91
15 mg
n=60
30 mg
n=60
60 mg
n=89

Confirmed Efficacy in Multiple Studies
Summary of Pain Intensity Differences (SPID)
*** p < 0.001 vs. Placebo
Dental Pain Study
p = 0.0682
p = 0.0392
Abdominal Laparoscopic Pain Study

17
0
20000
40000
60000
80000
100000
120000
140000
160000
180000
200000
-
10,000
20,000
30,000
40,000
50,000
60,000
70,000
80,000
***
***
***
***

Single 30 mg Dose Performance over 24 hrs
(Abdominal Hysterectomy
Trial

IV
Meloxicam)
Baseline Pain Level

60
18
-10
0
10
20
30
40
50
60
0
4
8
12
16
20
24
Time (Hours)
Placebo n=64
Morphine n=62
15 mg n=60
30 mg n=60
60 mg n=89

Well Tolerated
(Abdominal
Hysterectomy
Trial

IV
Meloxicam)

**Reported in
3% of Subjects in any group and greater than Placebo
Meloxicam
Placebo
n=64
Morphine
n=62
5 mg
n=60
7.5 mg
n=91
15 mg
n=60
30 mg
n=60
60 mg
n=89
Anemia
3.1
4.8
3.3
13.2
3.3
1.7
10.1
Anemia Postoperative
-
1.6
-
-
-
3.3
-
Constipation
-
4.8
5.0
1.1
1.7
-
-
Flatulence
-
4.8
1.7
1.1
3.3
-
-
Hypokalaemia

-
3.2
1.7
1.1
-
1.7
-
Insomnia
4.7
8.1
10.0
4.4
5.0
5.0
4.5
Ketonuria
7.8
9.7
6.7
9.9
15
10
10.1
Leukocytosis
-
-
1.7
-
-
3.3
-
Pyrexia
1.6
3.2
3.3
2.2
-
-
-
Sinus Tachycardia
-
-
3.3
-
-
-
1.1
Percent of Subjects Reporting an Adverse Event **
19

Next Steps for IV Meloxicam

Production of a clinical supply batch

Conduct Phase III Pivotal Study in hard and soft tissue models

Verify need for additional safety studies to meet adequate exposures / special populations	20

Dexmedetomidine
(Dex)

Dex
Has Demonstrated Analgesia & Safety

Alpha 2 agonist (non-opioid)

Injectable
form

(Precedex)
marketed
by
Hospira
in
US
as
sedative

Multiple studies demonstrating analgesia of alpha 2 agonists

Intranasal formulation in clinical development for acute
pain

In-licensed non-IV rights from Orion

Worldwide
rights
except
Europe,
Turkey,
and
CIS

Multiple
studies
demonstrate
Dex
pain
relief
and
safe
profile

Including our completed placebo controlled trials

Expect strong IP position

Pending IP coverage could run through 2030

Expect to file 505(b)(2) NDA after completion of Ph
III
22

Dex
Efficacy and Safety in Multiple Studies
Beneficial effects
Source
Approved sedative and safe profile
NDA filing / pivotal trials -
Abbott/Hospira, Orion

Morphine sparing
NDA studies plus Literature
Analgesia by IV route
Chan, 2010; Grosu, 2010; Lin, 2009, Arain, 2010
Demonstration of pain relief (VAS)
Placebo controlled trials; L. Webster, MD (Utah) CLBP study (Recro sponsored)
Positive PK/PD plasma levels demonstrating analgesic potential
Clinical trials run by Recro
Relieves morphine Max (hyperalgesia)
University of Minnesota; M. Belgrade, MD
23

Significant Advantages Over Opioids
Dex
Fast-acting Opioids
Non-opioid (Not controlled substance)
Opioid -
DEA scheduled product
No habituation effects

Addictive
Does not cause respiratory depression
Respiratory depression
Not associated with constipation,
nausea, or vomiting
Unwanted side-effects of constipation,
nausea and vomiting
Enhances morphine effectiveness
without morphine dose increase
Additive effect requires higher dose
More cognitively intact
Frequently Foggy / may be confused
Anxiolytic
properties
Not anxiolytic
Effective Analgesic
Effective Analgesic
24

Dex
Has Been Well Studied by Recro

Evaluated proprietary formulations of Dex
in 10 trials
Trial
Form

Design	Outcome
REC-14-013 Dex-IN Acute pain following bunionectomy surgery (n=168)	Statistically significant difference of SPID48 between 50 mcg of Dex-IN vs. placebo (p=0.0214)
REC-13-012 Dex-IN Acute pain following bunionectomy surgery (n=85 evaluable)	Within subset of patients (n=42), with baseline pain intensity of 6 or below, there was a trend towards analgesia in 50 mcg and reduced opioid use vs placebo
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

25

Dex-IN Study REC-14-013
(US placebo controlled trial)

Phase II bunionectomy
study

Randomized, placebo controlled study

Primary
endpoint

SPID48

Oral opioid rescue therapy allowed

Post Op Day 1 dosing

50 mcg of Dex-IN or placebo every 6 hours

84 patients in each treatment group (168 in total)

Additional secondary endpoints included:

Use of opioid rescue medication

SPIDs over various time intervals

Other standard efficacy analyses

Patients followed for 7 days after initial dosing
26

Study REC-14-013
(SPID48

Primary
Endpoint)
27
Note: Last Observation Carried Forward Analysis Method

p = 0.0214
0
500
1000
2000
2500
3000
Placebo N = 84
DEX-IN 50 µg N = 84
1500

Study REC-14-013
(Subject Characteristics)
Placebo
(N=84)
DEX-IN 50 µg
(N=84)
Female, n (%)

75 (89.3)
79 (94.0)
Age, Mean
44
43.9
(range)
(46 -
70)
(46 -
69)
Discontinued Subjects, n (%)
3 (3.6)
4 (4.8)
Lack of Efficacy
3 (3.6)
3 (3.6)
Adverse Event
0
1 (1.2)**
Race, n (%)
White
56 (66.7)
59 (70.2)
Black/African American
21 (25.0)
20 (23.8)
Other
7 (8.4)
5 (6.0)
Baseline PI Score, Mean
6.7
6.4
(range)
(4 -
10)
(4 -
10)
28
**Serious Adverse Event of Hypotension

Study REC-14-013
(Adverse Events
3 in Dex-IN Group)
29

If IV fluid given and no symptoms present, BP Decrease
recorded as AE

No medication given to any patient with BP or HR change

All nasal related AEs were rated as mild, except one case of nasal congestion rated as moderate

Adverse Event	Placebo (N=84)	DEX-IN 50 µg (N=84)
BP Decreased	3 (3.6%)	22 (26.2%)
Nausea	14 (16.7%)	13 (15.5%)
Nasal Discomfort	2 (2.4%)	7 (8.3%)
Headache	4 (4.8%)	6 (7.1%)
Vomiting	6 (7.1%)	4 (4.8%)
Nasal Dryness	3 (3.6%)	4 (4.8%)
Nasal Congestion	1 (1.2%)	4 (4.8%)
Nasal Obstruction	2 (2.4%)	3 (3.6%)
Bradycardia	0	3 (3.6%)
Dizziness	1 (1.2%)	3 (3.6%)
Hypotension	0	3 (3.6%)

Clinical Pipeline Intellectual Property

IV/IM meloxicam

formulation
IP
through

2022

Additional IP filed could run to 2030

Dex applications for methods for treating/preventing pain
through intranasal
and
sublingual
formulations
without
significant sedation

Fado
IP in-licensed from Orion

Composition of matter

Method of administration for analgesia

Treatment and prevention of hypotension and shock

Pro-Drug

Regulatory exclusivity

505(b)(2)

3
years
(Meloxicam,
Dex-IN,
Dex-SL)

505(b)(1)

NCE,
5
years
(Fado)
30

Fadolmidine
(Fado)

Fado
Effective in Phase II for Pain Relief

Alpha 2 agonist

more potent at the alpha 2c receptor than Dex

>20 fold less potent at the alpha 1b receptor than clonidine

Fado
has demonstrated analgesia in multiple animal models

Positive
Phase
II
analgesia
study
in
bunionectomy
patients

Intrathecal route of administration

Formulation work underway for topical prototype

Potential in regional neuropathies

WW rights to all human uses except Europe, Turkey and CIS

NCE
patent
w/
expected
extension
to
2021
/
pursuing
add 1
IP
32

Corporate Overview

US Based Manufacturing Facility
34

Manufacturing & Royalty Overview
Manufacturing
facility

87,000 sq. ft. solid oral dosage manufacturing cGMP

DEA licensed

~165 employees
Service capabilities

Formulation,
process
development
and
optimization

Process scale-up

Clinical supply and validation

Commercial supply
Ritalin LA

Once
daily ADHD treatment
marketed by Novartis
Focalin
XR

ADHD treatment marketed by Novartis
Verelan
/ verapamil

CV/High blood pressure treatment
marketed by Actavis
and UCB
Zohydro
ER

Extended release hydrocodone marketed by Pernix

Launched
in 2014

Abuse deterrent form launched
35

Strong Historical Manufacturing Performance

Carve-out financials

Zohydro
ER
abuse deterrent form launched

Additional capacity for new product opportunities

Positive cashflow
expected to cover all debt service
obligations and excess cashflows
to repay loan
principal
36
*EBITDA is a non-GAAP financial metric. Please see slide 38 for additional information including a reconciliation of Net Income to EBITDA.
(in millions)
12 months ended
Dec.
31, 2014
(audited)
3 months ended
March 31, 2015
3 months ended
March 31, 2014
Revenues
$75.2
$19.4
$16.6
EBITDA*
$29.2
$5.2
$6.8

Company Highlights

Multiple non-opioid therapeutics in mid to late stage clinical development for acute post operative pain

IV/IM
meloxicam

Phase
III
ready

long
acting,
demonstrated efficacy in successful Ph II trials

Dex-IN

proprietary,
intranasal
therapeutic
with
recently announced positive Ph II results

Revenue and cashflow
positive manufacturing &
royalty business

Experienced management team with significant
development, regulatory and commercial experience
37

Supplemental Financial Information
Non-GAAP Reconciliation
(in millions)
12 months
ended
Dec.
31, 2014

	(audited) 3 months ended March 31, 2015	3 months ended March 31, 2014
Net income	$14.3	$1.8	$3.5
Income tax expense	$3.3	$0.6	$0.8
Impairment of long-lived assets	$1.4	$0.0	$0.0
Depreciation and amortization	$10.3	$2.9	$2.5
EBITDA	$29.2	$5.2	$6.8

38

The Company defines EBITDA as earnings before interest, taxes, depreciation and amortization. The Company also presents EBITDA because it believes it is frequently used by securities analysts, investors and other interested parties as a measure of financial performance. EBITDA has limitations as an analytical tool, and when assessing the Company's operating performance, investors should not consider EBITDA in isolation, or as a substitute for net income (loss) or other consolidated income statement data prepared in accordance with U.S. GAAP.