

Recro Pharma, Inc.
Form FWP
February 13, 2014

Relieving Pain .Improving Lives
Issuer Free Writing Prospectus
Filed Pursuant to Rule 433
Registration No. 333-191879
February 13, 2014

Special Note Regarding Forward Looking
Statements

2

This presentation includes forward-looking statements within the meaning of the federal securities laws. 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, 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. We have described these risks in our Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission. Before you purchase any of our securities, you should read the Registration Statement to

obtain more complete information about our operations and business and the risks and uncertainties that we face in implementing our business plan. We assume no obligation to update any forward-looking statements except as required by applicable law.

Free Writing Prospectus Statement

3

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing.

We have filed a registration statement (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein)

and
other
documents
we
have
filed

with
the
SEC
for
more
complete
information
about
us and the offering.

You may get these documents for free by visiting EDGAR on the SEC Website at <http://www.sec.gov>. The preliminary prospectus, dated February 12, 2014, is available on the SEC Website at <http://www.sec.gov>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp, Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com.

Offering Summary

Issuer:

Recro Pharma, Inc.

Exchange / Ticker:

NASDAQ Capital Market / REPH

Shares Offered:

2,545,455 (100% primary)

Over-Allotment

15% or 381,818 (100% primary)

Price Range:

\$10.00 -

\$12.00 per share

Use of Proceeds:

Phase IIb and Phase III pivotal clinical trials, preclinical studies and safety trials, manufacturing work and working capital and

general corporate purposes

Sole Book-Runner:

Aegis Capital Corp

Co-Manager:

Brean Capital

4

Investment Highlights

Dex-IN
intranasal, non-opioid in Phase II for post-operative pain, a significant market opportunity

Multiple clinical studies demonstrate analgesic effect, fast onset of action and well tolerated

Multiple clinical and regulatory milestones over next few years

Expect to file 505(b)(2) NDA shortly after completion of Phase III

Experienced team with significant development,
regulatory and commercial experience

5

Experienced Management and Board

6

Gerri
Henwood

President
and
CEO

Founded Auxilium Pharmaceuticals (AUXL,
NASDAQ; revs ~\$400M (12); ~\$1bn market cap)
and IBAH (former NASDAQ Co., net revs \$130M
yr./gross revs >\$450 M/yr.
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*
Former SVP, Specialty Care Business Unit,
Pfizer
* Effective upon completion of IPO

Clinical Stage Pipeline

Product

PC

I

II

III

Rights

Dexmedetomidine (Dex)

WW, exc. Europe, Turkey, CIS*

Dex

-

IN

(intranasal)

Post-operative pain

Cancer breakthrough pain

Dex-SL (sublingual)

Transdermal

Fadolmidine (Fado)

WW, exc. Europe, Turkey, CIS*

Intrathecal

Post-operative pain

Topical

Neuropathic pain

7

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

Multiple Key Milestones Next Few Years

8

Event

Anticipated

Completion Timing

Post-Operative Pain Study

(6 month Phase IIb study in 150-180 pts)

2H 14

Post-Op Pain

Intra-Abdominal Surgery

(pivotal Phase III study; 6-9 months in 200+ pts)

2H 15

Post-Op Pain

Orthopedic Surgery

(pivotal Phase III study; 6-9 months in 200+ pts)

2H 15
NDA filing
Shortly after Ph III
NDA Approval
12 month review
period

Post-Op Pain Market Underserved

9

\$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.

Limited Pain Relief Options for Patients

10

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
Note: Pain severity based upon market research / physician feedback

11
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 post-op 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 shortly after completion of Ph III

12

Precedex®

Significant Growth in ICU Use

Growing interest among
anesthesiologists

Well understood and
effective

physician
familiarity with Dex

US patent expired Jan 14

Dex-IN PK/metabolism
create dosing complexities
13
Source: IMS Health

Dex Efficacy and Safety in Multiple Studies

14

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

Significant Advantages Over Opioids

15

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

Dex Has Been Well Studied by Recro
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
16

Evaluated proprietary formulations of Dex in 8
completed clinical trials

Dex-IN Study REC-11-010
(US placebo controlled POC trial)

24 chronic lower back pain (CLBP) patients

Chronic opioid users & non-opioid users

PBO controlled, cross-over to evaluate:

Analgesia
Standard VAS for Pain Intensity and Pain Relief at multiple
timepoints

Safety

Adverse
Events,
Vital
Signs,
Sedation

Single doses in a 3-way cross-over

PBO

Dex-IN 25 µg

Dex-IN 50 µg

Pain intensity measurements focused on 1 hour with
patients monitored for up to 24 hours

17

Fast Onset of and Prolonged Action

(Clinical trial REC-11-010

Dex-IN pharmacokinetics)

Note: Administered with single unit device

18

0

0.05

0.1

0.15

0.2

0.25

0

0.25

0.5

0.75

1
1.25
1.5
1.75
2
Time (hr)
DEX-IN 25µg
DEX-IN 50µg

Statistically Significant Pain Relief

(Dex-IN
REC-11-010)

Scale: 0 = No Relief, 4 = Complete Relief

*

*

*

* $p < 0.05$

** $p < 0.01$

19

0

0.5

1

1.5

2

2.5
BL
0.25
0.5
0.75
1
Time (hours)
DEX-IN PBO
DEX-IN 25µg
DEX-IN 50µg
*

Significant Pain Relief Over Time
(Dex-IN
REC-11-010
Summary Pain Intensity Differences)

* $p < 0.05$

20
0
1
2
3
4
5
6
7
8

0
0.25
0.5
0.75
1
Time (Hour)
DEX-IN PBO
DEX-IN 25µg
DEX-IN 50µg
*

Dex-IN
Pain
Scores
Comparative
-
1
hr
(Sublingual Sufentanil NanoTab
Major Abdominal Surgery)
Singla, Reg Anesth Pain Med 2010
21

Similar Dex-IN Pain Scores over 1 hr
(Sublingual Sufentanil NanoTab
Knee Replacement Surgery)
Skowronski, Reg Anesth Pain Med 2010
22

Select Opioid Clinical Trials Side Effects

23

Source: Stegmann et. al. (2008). The efficacy and tolerability of multiple-dose tapentadol immediate release for the relief of acute pain following orthopedic (bunionectomy) surgery.

Current Medical Research and Opinion

Placebo

Tapentadol IR

50mg

Tapentadol IR

100mg

Oxycodone IR

10mg

Event

n = 67

n = 67

n = 68

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%

Dex-IN Well Tolerated

(Clinical
trial

REC-11-010

-

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

Reported by more than one subject

24

Dex-IN Repeat Dosing Well Tolerated
(Clinical trial REC-11-008)

7 consecutive doses of 35 mcg Dex-IN every 6 hours

Evaluated heart rate, blood pressure and BP upon
standing every 5 minutes for two hours after dosing

Transient effect after initial dosing

None of the above effects categorized by
investigators as AEs

25

Well Tolerated Profile
Repeated Dosing
(Study REC-11-008
35 mcg Dex-IN formulation)
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
Number of Subjects
26

Dex-IN Next Steps in Post-Operative Pain

27

Initial commercial use: acute (5-7 days)

Planned Phase IIb bunionectomy study in 150-180 pts

Randomized, placebo controlled study

Primary endpoint summary of pain intensity scores (SPID)

Rescue therapy allowed

6 months from first subject dosed to data available

GLP toxicology studies

Pivotal post-op pain studies abdominal, orthopedic

Fadolmidine (Fado)
28

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
29

Corporate Overview
30

Intellectual property

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

Dex composition of oral transmucosal (SL) formulation and dispensing devices

Fado IP in-licensed from Orion

Composition of matter

Method of administration for analgesia

Treatment and prevention of hypotension and shock

Regulatory exclusivity

505(b)(2)

3 years (Dex-IN, Dex-SL)

505(b)(1)

NCE, 5 years (Fado)

31

Capitalization Structure

(Based upon expected closing date of March 12, 2014)

Capitalization

Shares

Outstanding

%

Outstanding

Common Stock

(1)

2,837,171

95%

Stock Options

(2)

152,182

5%

Fully-Diluted Shares Outstanding (prior to offering)

2,989,353

100%

32

(1)

Assumes automatic conversion of preferred stock and accrued dividends into an aggregate of 1,193,762 shares of common stock and conversion of outstanding bridge notes and accrued interest into an aggregate of 1,487,809 shares of common stock at an assumed IPO closing price of \$11.00 per share (the midpoint of the price range) and assuming the conversion occurs on March 12, 2014 (expected IPO closing date).

(2)

334,800 options outstanding at an exercise price of \$6.00. Assumes treasury stock method at an assumed IPO closing price of \$11.00 per share (the midpoint of the price range).

Note: 181,026 of new stock options will be issued to management at the IPO closing price upon closing of the IPO. Excludes warrants to be issued to Aegis upon completion of IPO. Warrants are exercisable at 150% of the IPO price.

Use of Proceeds / Dex-IN Next Steps

Expect to complete Phase IIb post-op pain trial

6 month study

Expect to complete both Phase III pivotal trials

Intra-abdominal study and orthopedic procedure study

6-9 month studies

Plan for NDA filing

Additional clinical safety data, preclinical tox and

CMC work

Working capital and general corporate purposes

33

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Experienced team with significant development,
regulatory and commercial experience

34