Recro Pharma, Inc.
Form POS AM
December 23, 2015
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As filed with the Securities and Exchange Commission December 23, 2015

Registration Statement No. 333-201841

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

RECRO PHARMA, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	2834	26-1523233
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

490 Lapp Road

Malvern, PA 19355

(484) 395-2400

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Gerri A. Henwood

President and Chief Executive Officer

Recro Pharma, Inc.

490 Lapp Rd

Malvern, PA 19355

(484) 395-2400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Rachael M. Bushey, Esq.

Pepper Hamilton LLP

3000 Two Logan Square

18th and Arch Streets

Philadelphia, PA 19103

(215) 981-4241

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company þ

The registrant is an emerging growth company, as defined in Section 2(a) of the Securities Act. This Registration Statement complies with the requirements that apply to an issuer that is an emerging growth company.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

On February 3, 2015, Recro Pharma, Inc., or the Company, filed a registration statement with the Securities and Exchange Commission, or SEC, on Form S-1 (Registration No. 333-201841), as amended, or the Registration Statement. The Registration Statement was declared effective by the SEC on February 13, 2015.

This Post-Effective Amendment No. 1 to Form S-1 is being filed by the Company to update the Registration Statement and contains an updated prospectus relating to the offering and sale of shares that were registered for resale pursuant to the Registration Statement.

All fees payable in connection with the registration of the shares of the Company s common stock, par value $0.01 per share, were paid by the registrant at the time of the initial filing of the Registration Statement.

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The information in this prospectus is not complete and may be changed. The selling shareholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and the selling shareholder is not soliciting offers to buy these securities in any state where the offer or sale of these securities is not permitted.

Subject To Completion, Dated December 23, 2015

PROSPECTUS

2,500,000 Shares

Common Stock

This prospectus relates to the sale of up to 2,500,000 shares of our common stock by Aspire Capital Fund, LLC, or Aspire Capital. Aspire Capital is also referred to in this prospectus as the selling shareholder. The prices at which the selling shareholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive proceeds of up to $10.0 million from the sale of our common stock to the selling shareholder, pursuant to a common stock purchase agreement entered into with the selling shareholder on February 2, 2015, referred to herein as the Purchase Agreement.

The selling shareholder is an underwriter within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling shareholder will be paid by the selling shareholder.

Our common stock trades on the NASDAQ Capital Market, or NASDAQ, under the ticker symbol REPH. On December 22, 2015, the last reported sale price per share of our common stock was $8.75 per share.

You should read this prospectus and any applicable prospectus supplement, together with additional information described under the heading Where You Can Find More Information, carefully before you invest in any of our securities.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE RISK FACTORS BEGINNING ON PAGE 6.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, and as such, we have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2015.

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You should read both this prospectus and any applicable prospectus supplement, including all documents incorporated by reference herein and therein, together with the additional information described under Where You Can Find More Information below.

The information contained in this prospectus is not complete and may be changed. You should rely only on the information provided in or incorporated by reference in this prospectus or in any applicable prospectus supplement, or documents to which we otherwise refer you. We have not authorized anyone else to provide you with different information.

We have filed or incorporated by reference exhibits to the registration statement of which this prospectus forms a part. You should read the exhibits carefully for provisions that may be important to you.

We have not authorized any dealer, agent or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any applicable prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or an accompanying prospectus supplement. This prospectus and the accompanying prospectus supplement, if any, do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying prospectus supplement, if any, constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement, if any, is accurate on any date subsequent to the date set forth on the front of such document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any applicable prospectus supplement is delivered or securities are sold on a later date.

References in this prospectus to the terms the Company, Recro, we, our and us or other similar terms mean Recr Pharma, Inc. and our wholly owned subsidiaries, unless we state otherwise or the context indicates otherwise.

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SUMMARY

This summary highlights certain information about us, this offering and selected information contained in the prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider the more detailed information in the prospectus, including Risk Factors and the financial statements and related notes.

Overview

Our Business

We are a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain. Our lead product candidate intravenous or intramuscular, or IV/IM, meloxicam is ready to begin pivotal Phase III clinical trials for the management of acute post-operative pain. IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for moderate to severe acute pain has successfully completed multiple Phase II clinical trials. We believe IV/IM meloxicam compares favorably to competitive therapies in onset of pain relief, duration of pain relief, extent of pain relief and time to peak analgesic effect. Based on feedback from the U.S. Food and Drug Administration, or FDA, we intend to initiate a Phase III program that will include two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,200 patients in these trials. One pivotal clinical trial will be designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model, and the other pivotal trial will be designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model. Our pipeline also includes Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, which successfully completed a Phase II clinical trial in post-operative pain. In October 2015 we met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed Dex clinical development program. Based on feedback from the FDA regarding Dex s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we believe that such a program is not advisable due to time, cost and associated risk. We plan to reevaluate Dex as discussed with the FDA and intend to pursue a Phase II program in peri-procedural pain. Dex is a selective alpha-2 adrenergic agonist that has demonstrated analgesic properties in multiple studies. If approved, Dex would also be the first and only approved peri-procedural pain drug in its class of drugs. As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory distress, and constipation while maintaining analgesic, or pain relieving, effect.

We currently own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®; as well as development stage products.

We have a limited operating history. We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $30.3 million. On July 7, 2015, we closed a private placement with certain accredited investors in which we sold 1,379,311 shares of common stock at a price per share of $11.60, for net proceeds of approximately $14.8 million. We paid the placement agents a fee equal to 6.0% of the

aggregate gross proceeds from the private placement, plus reimbursement of certain expenses.

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We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2015, we had an accumulated deficit of $41.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing and clinical trials. We expect to incur increasing expenses over the next several years to develop IV/IM meloxicam and Dex, including the planned Phase III pivotal and safety trials for IV/IM meloxicam and Phase II trials for Dex-IN. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of IV/IM meloxicam and Dex.

We expect that annual results of operations will fluctuate for the foreseeable future due to several factors. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

On April 10, 2015, we completed our acquisition from Alkermes plc, or Alkermes, of certain assets, including the worldwide rights to IV/IM meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and the increase in our workforce as a result of the addition of the Gainesville employees.

Under the terms of the purchase and sale agreement with Alkermes, we paid Alkermes $52.7 million at closing, net of cash acquired. Alkermes is entitled to receive up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales, in each case, related to IV/IM meloxicam. Upon closing, we issued to Alkermes a warrant to purchase an aggregate of 350,000 shares of our common stock at an exercise price of $19.46 per share. The $52.7 million up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with OrbiMed Royalty Opportunities II, LP, or OrbiMed, and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

Our Intellectual Property

We own a patent portfolio directed to the sale, use, manufacturing, and formulating of IV/IM meloxicam. The patent protection for IV/IM meloxicam could provide for protection of IV/IM meloxicam through 2030, subject to any extensions or disclaimers.

We own a patent portfolio and exclusively license patents and patent applications from Alkermes directed to the composition, manufacturing, and formulating of Zohydro ER. The patent protection for Zohydro ER could lead to protection of Zohdyro ER through 2034, subject to any extensions or disclaimers.

We have an exclusive license from Orion to commercialize Dex as a therapeutically active ingredient for use in the treatment of pain in humans in any dosage form for a variety of delivery vehicles (except for administration by injection or infusion) worldwide other than Europe, Turkey, and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. We also have an exclusive license from Orion for Fado for use in humans in any dosage form. One focus of our claims strategy is on formulation claims and method of treatment claims. The Dex patent application family includes three portfolios of pending patent applications, one for each of sublingual, topical/transdermal, and intranasal formulations of Dex. Our strategy, if successful in obtaining patent protection, could lead to protection of our product candidates through 2030 subject to any extensions or disclaimers. See the Business Intellectual Property section of this prospectus for more information.

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Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. See the Risk Factors section of this prospectus for a discussion of such risks.

Corporate Information

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2470. Our website address is *www.recropharma.com*. The information contained in, or accessible through, our website does not constitute part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- being permitted to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- reduced disclosure about our executive compensation arrangements, including no Compensation Discussion and Analysis;
- exemption from the requirement of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act of 2002.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earlier of (1) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (2) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering of our common stock, or our IPO, which we completed March 12, 2014; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC.

To the extent that we continue to qualify as a smaller reporting company, as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of our internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act of 2002; (2) reduced executive compensation disclosures; and (3) being permitted to provide only two years of audited financial statements, instead of three years.

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The Offering

Common stock offered by the selling shareholder	Up to 2,500,000 shares
Common stock outstanding	9,224,315 shares (as of December 22, 2015)
Use of proceeds	The selling shareholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive up to $10.0 million in proceeds from the sale of our common stock to the selling shareholder under the common stock purchase agreement described below. Any proceeds from the selling shareholder that we receive under the purchase agreement are expected be used to fund the development of our clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures, acquisitions of businesses, products or technologies, and funding our working capital needs.
NASDAQ Capital Market symbol	REPH
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the Risk Factors section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

The number of shares of our common stock outstanding excludes 2,060,343 shares of our common stock issuable upon the exercise of stock options outstanding as of December 22, 2015 at a weighted-average exercise price of $7.58 per share; 32,200 shares of our common stock issuable upon the settlement of restricted stock units outstanding as of December 22, 2015; 174 additional shares of our common stock available for future issuance as of December 22, 2015 under our 2008 Stock Option Plan; 977,698 shares of our common stock available for future issuance under our Amended and Restated Equity Incentive Plan; and 784,928 shares of our common stock issuable upon the exercise of outstanding warrants with weighted average exercise price of $12.05 per share.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above.

On February 2, 2015, we entered into a common stock purchase agreement (referred to in this prospectus as the Purchase Agreement), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as Aspire Capital or the selling shareholder), which provides that, upon the terms and subject to the

conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the approximately 24-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 96,463 shares of our common stock as a commitment fee (referred to in this prospectus as the Commitment Shares). Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital (referred to in this prospectus as the Registration Rights Agreement), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

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As of December 22, 2015, there were 9,224,315 shares of our common stock outstanding (3,866,633 shares held by non-affiliates). If all of the 2,500,000 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 21.5% of the total common stock outstanding or 39.9% of the non-affiliate shares of common stock outstanding as of the date hereof. The aggregate number of shares that we can issue to Aspire Capital under the Purchase Agreement may in no case exceed 1,540,749 shares of our common stock (which is equal to approximately 19.99% of the common stock outstanding on the date of the Purchase Agreement), unless (i) shareholder approval is obtained to issue more, in which case this 1,540,749 share limitation will not apply, or (ii) shareholder approval has not been obtained and at any time the 1,540,749 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Purchase Agreement (including the Commitment Shares) is equal to or greater than $2.81, or the Minimum Price, a price equal to the closing sale price of our common stock on the business date of the execution of the Purchase Agreement; provided that at no point in time shall Aspire Capital (together with its affiliates) beneficially own more than 19.99% of our common stock.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,500,000 shares of our common stock under the Securities Act, which includes the Commitment Shares that have already been issued to Aspire Capital and 2,403,537 shares of common stock which we may issue to Aspire Capital after the date hereof. All 2,500,000 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 2,500,000 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 2,500,000 shares of common stock offered hereby.

After the SEC has declared effective the registration statement of which this prospectus is a part, on any trading day on which the closing sale price of our common stock exceeds $0.50, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, each a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $500,000 per trading day, up to $10.0 million of our common stock in the aggregate at a per share price, or the Purchase Price, calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 50,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $0.50 per share of Common Stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, each a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company s common stock traded on the NASDAQ on the next trading day, or the VWAP Purchase Date, subject to a maximum number of shares we may determine, or the VWAP Purchase Share Volume Maximum, and a minimum trading price, or the VWAP Minimum Price Threshold (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice, or the VWAP Purchase Price, is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50 per share, or the Floor Price. The Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The

Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

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RISK FACTORS

Our business is influenced by many factors that are difficult to predict, and that involve uncertainties that may materially affect actual operating results, cash flows and financial condition. Before making an investment decision, you should carefully consider these risks, including those set forth in the Risk Factors section of our most recent Annual Report on Form 10-K filed with the SEC, as revised or supplemented by our Quarterly Reports on Form 10-Q filed with the SEC since the filing of our most recent Annual Report on Form 10-K, each of which is incorporated by reference into this prospectus. You should also carefully consider any other information we include or incorporate by reference in this prospectus or include in any applicable prospectus supplement. Each of the risks described in these sections and documents could materially and adversely affect our business, financial condition, results of operations and prospects, and could result in a partial or complete loss of your investment.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing shareholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We are registering for sale 96,463 Commitment Shares and 2,403,537 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 14 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all, some or none of the $10.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain, and any applicable prospectus supplement and the documents incorporated therein may contain, forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus, any applicable prospectus supplement or the documents incorporated herein and therein by reference regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, predict, project, will, would and similar expressions are intended to identify forward-looking statements, although n all forward- looking statements contain these identifying words.

The forward-looking statements in this prospectus and the documents incorporated herein by reference include, among other things, statements about:

- the results and timing of our clinical trials of IV/IM meloxicam, Dex or our other product candidates, and any future clinical and preclinical studies;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval that we may obtain;
- regulatory developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- our ability to raise future financing for continued development;
- the performance of our third-party suppliers and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights;
- our ability to successfully implement our strategy;
- our ability to maintain our relationships and contracts with our commercial partners;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance;

our ability to successfully integrate our acquisition of certain assets acquired in the Gainesville Transaction; and

our ability to meet required debt payments and operate under increased leverage and associated lending covenants.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly under Risk Factors, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this prospectus, any applicable prospectus supplement and the documents that we incorporate by reference herein and therein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

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THE ASPIRE CAPITAL TRANSACTION

General

On February 2, 2015, we entered into the Purchase Agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement with Aspire Capital, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 22, 2015, there were 9,224,315 shares of our common stock outstanding (3,866,633 shares held by non-affiliates). If all of such 2,500,000 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 25.1% of the total common stock outstanding or 39.9% of the non-affiliate shares of common stock outstanding as of the date hereof. The aggregate number of shares that we can issue to Aspire Capital under the Purchase Agreement may in no case exceed 1,540,749 shares of our common stock (which is equal to approximately 19.99% of the common stock outstanding on the date of the Purchase Agreement), unless (i) shareholder approval is obtained to issue more, in which case this 1,540,749 share limitation will not apply, or (ii) shareholder approval has not been obtained and at any time the 1,540,749 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Purchase Agreement (including the Commitment Shares) is equal to or greater than $2.81, or the Minimum Price, a price equal to the closing sale price of our Common Stock on the business date of the execution of the Purchase Agreement; provided that at no one point in time shall Aspire Capital (together with its affiliates) beneficially own more than 19.99% of our common stock.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,500,000 shares of our common stock under the Securities Act, which includes the Commitment Shares that have already been issued to Aspire Capital and 2,403,537 additional shares of common stock which we may issue to Aspire Capital after the date hereof. All 2,500,000 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 2,500,000 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 2,500,000 shares of common stock offered hereby.

On any trading day on which the closing sale price of our common stock is not less than $0.50 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per business day, up to $10.0 million of our common stock in the aggregate at a purchase price calculated by reference to the prevailing market price of our common stock over the preceding 12-business day period (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 50,000 shares of our common stock and our stock price is not less than $0.50 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

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The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. Aspire Capital may not assign its rights or obligations under the Purchase Agreement.

Purchase Of Shares Under The Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds $0.50 per share, we may direct Aspire Capital to purchase up to 50,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 50,000 shares, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of our common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by us in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the closing sale price of our common stock on the VWAP Purchase Date; or
- 95% of the volume-weighted average price for our common stock traded on the NASDAQ:
  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum; or
  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of our common stock falls below the VWAP Minimum Price Threshold.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the purchase price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than $0.50 per share.

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Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of shares of our common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of 30 business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than 30 consecutive business days, with an extension for up to an additional 30 days if we receive a comment letter from the SEC in connection with such post-effective amendment;

- the suspension from trading or failure of our common stock to be listed on our principal market for a period of three consecutive business days;

- the delisting of our common stock from the NASDAQ, and our common stock not immediately thereafter being listed and traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Over-The-Counter Bulletin Board interdealer quotation system or either one of the OTCQB or the OTCQX market places of the OTC Markets Group, Inc.;

- our transfer agent s failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

- any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;

- our becoming insolvent or generally unable to pay our debts as they become due; or

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Shareholders; Dilution

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 2,500,000 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 14 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 2,403,537 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all,

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some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $10.0 million shares of our common stock. However, we estimate that we will sell no more than 2,500,000 shares to Aspire Capital under the Purchase Agreement (including the 96,463 Commitment Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 2,500,000 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 2,500,000 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering (in millions)	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price (in millions)(1)	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (2)
$ 0.50	$ 0.7	1.4	14%
$ 1.00	$ 1.4	1.4	14%
$ 2.00	$ 2.9	1.4	14%
$ 3.00	$ 7.2	2.4	22%
$ 4.00	$ 9.6	2.4	22%
$ 6.00	$ 10.0	1.7	16%
$ 8.00	$ 10.0	1.3	13%
$ 9.00	$ 10.0	1.1	12%

(1) Excludes the Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital.

(2) The denominator is based on 9,224,315 shares outstanding as of December 22, 2015 (including Commitment Shares previously issued to Aspire Capital) and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding assumed purchase price set forth in the adjacent column.

The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

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USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to $10.0 million under the Purchase Agreement with Aspire Capital.

We anticipate that the net proceeds received from the sale of shares of common stock under the Purchase Agreement will be used to fund the development of our clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding our working capital needs. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. Pending such uses, we may invest the net proceeds in investment grade interest-bearing securities.

The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including the amount and timing of the proceeds under the Purchase Agreement and progress with our clinical development programs. Expenditures will also depend upon the establishment of collaborative arrangements with other companies, the availability of additional financing and other factors. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. There can be no guarantee that we will ever pay any dividends.

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SELECTED FINANCIAL DATA

This section should be read together with our financial statements and accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 and filed with the SEC on March 25, 2015 and our Quarterly Report on Form 10-Q for the period ending September 30, 2015 and filed with the SEC on November 13, 2015, which are incorporated by reference into this prospectus. We derived the selected statements of operations data for the years ended December 31, 2013 and 2014 and the selected balance sheet data as of December 31, 2013 and 2014 from our audited financial statements and accompanying notes incorporated by reference into this prospectus. The selected financial data as of and for the year ended December 31, 2012 is derived from audited financial statements not included in our Annual Report on Form 10-K. We derived the selected statements of operations data for the nine months ended September 30, 2014 and 2015 and the selected balance sheet data as of September 30, 2015 from our unaudited consolidated financial statements and accompanying notes incorporated by reference into this prospectus. The selected financial data in this section are not intended to replace our financial statements and the related notes. The unaudited financial data, in management s opinion, have been prepared on the same basis as the audited financial statements and related notes incorporated by reference in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected in the future and results from our interim period may not necessarily be indicative of the results of the entire year.

	Year ended December 31,			Nine months ended September 30,	
	2014	2013	2012	2015	2014
	(in thousands, except share and per share data)				
Statements of Operations Data:					
Revenue:					
Manufacturing, royalty and profit sharing revenue	$	$	$	$ 32,824	$
Research and development revenue				2,375	
Total revenue				35,199	
Operating expenses:					
Cost of sales (excluding amortization of intangible assets)				19,228	
Research and development	7,874	544	542	7,260	5,619
General and administrative	3,998	546	339	8,492	2,768
Amortization of intangible assets				1,238	
Change in warrant valuation				119	
Change in contingent consideration				2,586	
Total operating expenses	11,872	1,090	881	38,923	8,387
Operating loss	(11,872)	(1,090)	(881)	(3,724)	(8,383)
Other income (expense):					
Interest income	10			10	7
Grant income			85		

Interest expense	(4,272)	(868)	(740)	(3,888)	(4,273)
	(4,262)	(868)	(655)	(3,878)	(4,266)
Net loss	(16,134)	(1,958)	(1,536)	(7,602)	(12,653)
Accretion of redeemable convertible preferred stock	(1,270)	(440)	(413)		(1,270)
Net loss applicable to common shareholders	$ (17,404)	$ (2,398)	$ (1,949)	$ (7,602)	$ (13,923)
Basic and diluted net loss per common share	$ (2.79)	$ (15.41)	$ (12.53)	$ (0.92)	$ (2.42)
Weighted average basic and diluted common share outstanding	6,238,581	155,600	155,600	8,243,909	5,743,527
Unaudited pro forma net loss	$ (11,861)				
Unaudited pro forma basic and diluted net loss per common share(1)	$ (1.73)				
Unaudited pro forma weighted average basic and diluted common shares outstanding(1)	6,861,570				

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(1) See Note 3(g) to our audited financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 and filed with the SEC on March 25, 2015 regarding computation of unaudited pro forma basic and diluted net loss per common share and the unaudited pro forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

	As of December 31,			As of September 30,
	2014	2013	2012	2015
		(in thousands)		
Balance Sheet Data:				
Cash and cash equivalents	$ 19,682	$ 13	$ 53	$ 28,275
Working capital	18,929	(12,080)	(10,123)	29,307
Total assets	20,374	851	154	134,510
Debt		11,907	10,159	38,022
Series A redeemable convertible preferred stock		5,880	5,440	
Total shareholders equity (deficit)	18,929	(17,960)	(15,562)	28,376

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BUSINESS

Overview

We are a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain. Our lead product candidate intravenous or intramuscular, or IV/IM, meloxicam is ready to begin pivotal Phase III clinical trials for the management of acute post-operative pain. IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for moderate to severe acute pain has successfully completed multiple Phase II clinical trials. The oral form of meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990 s as Mobic®. We believe IV/IM meloxicam compares favorably to competitive therapies in onset of pain relief, duration of pain relief, extent of pain relief and time to peak analgesic effect. Based on feedback from the U.S. Food and Drug Administration, or FDA, we intend to initiate a Phase III program that will include two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,200 patients in these trials. One pivotal clinical trial will be designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model, and the other pivotal trial will be designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model.

Our pipeline also includes Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, which successfully completed a Phase II clinical trial in post-operative pain. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, is an FDA approved and commercial injectable drug sold by Hospira, Inc. in the United States under the brand name Precedex® and by Orion in Europe under the brand name Dexdor®. In October 2015 met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we believe that such a program is not advisable due to time, cost and associated risk. We plan to reevaluate Dex-IN as discussed with the FDA and intend to pursue a Phase II program in peri-procedural pain. If approved, Dex-IN would also be the first and only approved peri-procedural pain drug in its class of drugs.

As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory distress, and constipation while maintaining analgesic, or pain relieving, effect. We are pursuing a Section 505(b)(2) regulatory strategy for IV/IM meloxicam and Dex-IN.

We also have a sublingual formulation of Dex, Dex-SL, which may be appropriate for use in treating chronic pain. In addition to Dex, we have a second selective alpha-2 agonist product candidate in development, Fado, which has been shown to be effective in a post-bunionectomy Phase II pain study conducted by Orion. Based on preclinical data, we believe Fado also shows promise in neuropathic pain.

We own the worldwide rights to IV/IM meloxicam, which we acquired from Alkermes plc, or Alkermes, in April 2015. Under our license with Orion, upon regulatory approval we will have commercial rights for Dex-IN and Dex-SL in the Territory, for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for an administration by injection or infusion. Similarly, under our license agreement with Orion, upon regulatory approval, we will have commercial rights related to Fado in the Territory, for all indications in humans.

In summary, our product candidates for pain indications include:

IV/IM meloxicam, a product candidate in development for the treatment of acute post-operative pain;

Dex-IN, a product candidate in development for the treatment of acute peri-procedural pain;

Dex-SL, a product candidate for the treatment of chronic pain; and

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Fado, a product candidate used by injection into the spine for pain associated with surgery or certain types of chronic pain associated with nerve damage to local tissues (neuropathies), especially of the lower extremities, which can occur in diabetic patients.

Pipeline

We currently own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®; as well as development stage products.

Background

We have a limited operating history. We were incorporated in 2007 with the intention of pursuing products for non-opioid treatment of serious pain. In 2008 and 2010, we entered our license agreements with Orion pursuant to which we acquired our rights to Dex and Fado, respectively.

We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $30.3 million. On July 7, 2015, we closed a private placement with certain accredited investors in which we sold 1,379,311 shares of common stock at a price per share of $11.60, for net proceeds of approximately $14.8 million. We paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the private placement, plus reimbursement of certain expenses.

We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2015, we had an accumulated deficit of $41.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing and clinical trials. We expect to incur increasing expenses over the next several years to develop IV/IM meloxicam and Dex, including the planned Phase III pivotal and

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safety trials for IV/IM meloxicam and Phase II trials for Dex-IN. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of IV/IM meloxicam and Dex.

We expect that annual results of operations will fluctuate for the foreseeable future due to several factors. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

On April 10, 2015, we completed our acquisition from Alkermes of certain assets, including the worldwide rights to IV/IM meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and increase in our workforce as a result of the addition of the Gainesville employees.

Under the terms of the purchase and sale agreement with Alkermes, we paid Alkermes $52.7 million at closing, net of cash acquired. Alkermes is entitled to receive up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales, in each case, related to IV/IM meloxicam. Upon closing, we issued to Alkermes a warrant to purchase an aggregate of 350,000 shares of our common stock at an exercise price of $19.46 per share. The $52.7 million up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with OrbiMed Royalty Opportunities II, LP, or OrbiMed, and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

Post-Operative Pain Market Overview

Based upon statistics from the National Center for Health Statistics, it is estimated that there are over 100 million surgeries performed in the United States each year. Of these surgeries, we believe at least 50 million procedures require post-operative pain medication. While opioids are generally considered the most effective treatment for post-operative pain, they raise serious concerns due to addiction, illicit use, respiratory depression and other side effects, including constipation, nausea, vomiting, and intolerance. Due to their addictive potential, opioids are regulated as controlled substances and are listed on Schedule II and III by the DEA. As a result of these side effects, pain sufferers tend to limit their use of opioids, resulting in as many as 40% of post-operative patients reporting inadequate pain relief. This reduces the quality of life for individuals and creates an economic burden estimated to be at least $560 to $635 billion a year in medical costs and lost productivity. According to the CDC, overdose deaths from prescription painkillers (defined by the CDC to mean opioid or narcotic pain relievers, including drugs such as Vicodin (hydrocodone), OxyContin (oxycodone), Opana (oxymorphone), and methadone) has increased significantly over the past 10 years. It notes the following trends:

- Prescription painkiller overdoses killed nearly 15,000 people in the United States in 2008, more than 3 times the 4,000 people killed by these drugs in 1999;

- In 2010, about 12 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year;

Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers; and

Nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

We believe that IV/IM meloxicam offers an attractive alternative for pain relief without the risks associated with opioids. Accordingly, we believe that physicians and third-party payors, including Medicare and Medicaid, are highly interested in new non-opioid pain therapies that provide effective pain relief without the issues associated with opioids.

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We also believe that Dex-IN offers an option for patient management prior to, during and following short clinical procedures associated with pain, anxiety and discomfort that are performed in settings where IV access is not typically available.

Cancer Breakthrough Pain Market Overview

In addition to peri-procedural pain relief, we believe Dex-IN may provide a good alternative therapeutic for cancer breakthrough pain relief. It is estimated that 80% of patients taking long-acting medication for chronic pain experience breakthrough pain. Breakthrough pain comes on very rapidly and can last from three to 30 minutes. Currently, cancer breakthrough pain is primarily treated with fast acting opioids mainly fentanyl, such as Fentora® and Actiq® (marketed by Teva Pharmaceutical Industries Ltd.). However, because these therapeutics are opioids, they raise the same concerns discussed above.

Our Strategy

We intend to maximize the value of our development candidates. This strategy could include developing our candidates through approval and ultimately self-commercialization, out-licensing, partnering on certain assets, or selling the Company or the assets. We believe our product candidates and their proposed indications target a narrow group of specialist prescribers which would allow for the successful marketing and commercialization of the product candidates by a company of our size. However, Dex-SL may target a broader group of prescribers and, if so, will likely require a partner. Our broader corporate strategy includes the following:

Focus on developing IV/IM meloxicam for acute post-operative pain. Our key goal is to file a new drug application, or NDA, and receive FDA approval of IV/IM meloxicam for the management of moderate to severe pain. Based on feedback from the FDA, we intend to initiate a Phase III program that will include two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,200 patients in these trials. One pivotal clinical trial will be designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model, and the other pivotal trial will be designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model. We believe developing IV/IM meloxicam for the management of moderate to severe pain indication provides us the fastest and best path to building a specialty pharmaceutical company focused on options for pain management. Therefore, we are initially concentrating our management focus and resources on attaining this goal.

Evaluate Dex-IN for use in short clinical procedures associated with pain, anxiety and discomfort that are performed in settings where IV access is not typically available. We plan to reevaluate Dex-IN as discussed with the FDA and intend to pursue a Phase II program in peri-procedural pain.

Expand our manufacturing business by adding additional manufacturing programs for commercial products through business development efforts as well as expanding development of proprietary drug formulations and entering into commercialization agreements with third-party commercial partners. We now own and operate a DEA-licensed facility that currently manufactures five commercial products for pharmaceutical partners, and we intend to seek additional commercial partners.

Leverage our management development experience for other indications and product candidates. If we have sufficient additional resources, we plan to progress our existing drug candidates as well as those we may identify in the future for potential additional indications.

Enter into strategic partnerships to maximize the potential of our product candidates outside of the United States. We intend to pursue strategic collaborations with other pharmaceutical companies to develop and commercialize our

product candidates outside of the United States. We believe that our management expertise and unique product candidates make us an attractive partner to potential strategic companies.

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Meloxicam Overview

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses anti-inflammatory, analgesic, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase, or COX, and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990 s as an oral agent, Mobic®. Mobic tablets and suspension are indicated for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis and the relief of the signs and symptoms of pauciarticular or polyarticular course juvenile rheumatoid arthritis in patients 2 years or older.

Meloxicam has a slow onset of action orally, and is not currently approved for the treatment of acute pain. The oral form has a prolonged absorption time, with the time of maximum observed plasma concentration (tmax) being approximately 5-6 hours following oral administration, which is consistent with its poor aqueous solubility. Our proprietary injectable form of the drug, which utilizes NanoCrystal technology, provides a faster onset of action of meloxicam, thus providing a rapid and sustained treatment of acute pain via the intravenous (IV) or intramuscular (IM) administration routes.

IV/IM Meloxicam Advantages over Injectable Therapeutics

We believe IV/IM meloxicam has a number of advantages over existing, FDA approved non-opioid analgesics, including ketorolac, ibuprofen and acetaminophen, including the following:

Not considered a controlled substance. Meloxicam is not an opioid. Opioid therapeutics are currently controlled by the DEA under the Controlled Substances Act. Under this act, opioids have been scheduled based on their potential for abuse and/or addiction. For those opioids placed in Schedule II, federal law prohibits the refilling of prescriptions, thus requiring patients to request and physicians to write additional prescriptions for each refill. Examples of Schedule II opioids include codeine, fentanyl, sufentanil, hydrocodone and oxycodone.

Does not cause respiratory depression. Meloxicam does not cause respiratory depression. Besides the addictive nature of opioids, we believe that medical practitioners are highly concerned with respiratory depression, which is a well-documented side effect of opioid use (all opioids including fentanyl and oxycodone). Respiratory depression is defined by decreased lung ventilation leading to increased carbon dioxide and can be life threatening. Meloxicam has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Onset of pain relief. While the oral form of meloxicam can take 60 minutes or more for pain relief, the utilization of NanoCrystal™ technology in the IV/IM formulation results in a more rapid onset of pain relief of less than 10 minutes. Ketorolac, for example, can take up to 40 minutes for the onset of pain relief.

Duration of pain relief. IV/IM meloxicam utilizing NanoCrystal™ technology has demonstrated the potential to be an effective analgesic for up to 18 to 24 hours on a single injectable dose in clinical trials. IV forms of ketorolac, ibuprofen and acetaminophen last 4 to 6 hours in effective pain relief resulting in the need of 4 to 6 doses for every 24 hours of pain relief.

Time to peak analgesic effect. Clinical data has demonstrated that IV/IM meloxicam reaches peak analgesic effect within approximately 40 minutes, reaching its peak faster than competing non-opioid therapeutics. Ketorolac can take between 1 to 2 hours to reach its peak analgesic effect.

Additionally, we believe that IV/IM meloxicam has an administration advantage in terms of time of infusion whereas ibuprofen and acetaminophen can take up to 15 to 30 minutes to infuse. Neither ibuprofen nor acetaminophen

currently have intramuscular formulations.

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Clinical Trial Overview

Six clinical trials evaluating the safety, pharmacokinetics and analgesic potential of IV/IM meloxicam have been conducted for IV/IM meloxicam. An ascending dose safety and pharmacokinetic study in healthy subjects; a Phase II dose-finding analgesic study following third molar surgery; a multiple ascending dose safety and pharmacokinetics study in healthy subjects; a Phase II analgesic study in open abdominal hysterectomy; and a Phase II multiple dose analgesic study following laporascopic abdominal surgery were conducted evaluating IV administration. In addition, a multiple ascending dose safety and pharmacokinetic study in healthy subjects was conducted evaluating IM administration. Based upon the results of these trials, we believe that IV/IM meloxicam has the potential to be a potent analgesic in the management of moderate to severe pain.

Pharmacokinetic Studies

Three pharmacokinetic studies have examined single and multiple doses of IV/IM meloxicam. In general terms, IV/IM administration resulted in peak plasma concentrations immediately follow dosing. When compared to oral Mobic, IV meloxicam had similar areas under the plasma drug concentration-time curve and half-lives for doses of 15 mg, 30 mg and 60 mg.

Study N1539-04

This was a Phase II, multicenter, randomized, double-blind, placebo-and active-controlled study in 486 female subjects who underwent open abdominal hysterectomy. Subjects received a single dose of either IV placebo, morphine or meloxicam 5 mg, 7.5 mg, 15 mg, 30 mg or 60 mg. Following surgery on post-operative day, or Post Op Day, 1 subjects reported when their pain reached a moderate or severe level on a 4-point Likert Scale (with categories of none, mild, moderate, or severe). They were then asked to indicate their pain intensity, or PI, on a 100-mm Visual Analog Scale, or VAS. Subjects who rated their pain as moderate or severe and ³45 mm were randomized and treated. Starting at the time of study drug administration and continuing for 24 hours thereafter, subjects had access to rescue medication. During the 24-hour double-blind evaluation period, efficacy measurements of PI and pain relief, or PR, were made using the 100-mm VAS to assess PI and a 5-point categorical scale (ranging from none to complete) to assess PR.

Overall, all active treatment doses produced statistically significant reductions in sum of pain intensity differences, or SPID, over 24 hours, or SPID24 (a co-primary endpoint) compared to placebo ($P < 0.001$). In addition, all active treatment doses also produced statistically significant improvement in $TOTPAR_{24}$ (a co-primary efficacy endpoint) compared to placebo ($P < 0.001$). Statistically significant decreases in PI from baseline were detected as early as 10 minutes postdose and continued throughout the 24 hour postdose period. In general, the greatest decreases were seen in the 30 mg and 60 mg dose groups followed by the 15 mg group (Figure 1).

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Figure 1: Pain Intensity Differences at Various Time Points

Rescue medication use during the 24-hour double-blind period was reduced by approximately 90% in the meloxicam 30 mg and 60 mg dose groups, and by 86%, 77%, 81%, and 71% in the 15 mg, 7.5 mg, 5 mg, and morphine groups, respectively, compared to placebo. Statistically significant differences were seen between each active group and placebo ($P < 0.001$). The percentage of subjects using rescue medication is presented in Figure 3. The median time to rescue (based on the lower bound of the 95% confidence interval for the 50^{th} percentile) was greatest for meloxicam 30 mg (21.9 hours), followed by 60 mg (20.6 hours), 15 mg (18.3 hours), 5 mg (12.2 hours), 7.5 mg (8.3 hours), morphine (6.6 hours), and placebo (1.1 hours).

Figure 2: Percentage of Subjects Using Rescue Medication

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Study medication was well tolerated. A total of five serious adverse events, or SAEs, were reported in the study, and none were assessed as related to treatment. There were no clinically meaningful trends in vital signs, electrocardiograms or laboratory assessments. Adverse events were generally low and consistent with this surgical population (Table 1).

Table 1: Adverse Events reported by ³3% of subjects from any treatment group

			Meloxicam IV				
	Placebo N = 64 n (%)	**Morphine N = 62 n (%)**	**5 mg N = 60 n (%)**	**7.5 mg N = 91 n (%)**	**15 mg N = 60 n (%)**	**30 mg N = 60 n (%)**	**60 mg N = 89 n (%)**
Anemia	2 (3.1)	3 (4.8)	2 (3.3)	12 (13.2)	2 (3.3)	1 (1.7)	9 (10.1)
Leukocytosis	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	0 (0.0)	2 (3.3)	0 (0.0)
Sinus tachycardia	0 (0.0)	0 (0.0)	2 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)
Abdominal distension	2 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	0 (0.0)	3 (4.8)	3 (5.0)	1 (1.1)	1 (1.7)	0 (0.0)	0 (0.0)
Flatulence	0 (0.0)	3 (4.8)	1 (1.7)	1 (1.1)	2 (3.3)	0 (0.0)	0 (0.0)
Nausea	2 (3.1)	1 (1.6)	1 (1.7)	1 (1.1)	1 (1.7)	1 (1.7)	2 (2.2)
Pyrexia	1 (1.6)	2 (3.2)	2 (3.3)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)
Anemia post-operative	0 (0.0)	1 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.3)	0 (0.0)
Hypokalemia	0 (0.0)	2 (3.2)	1 (1.7)	1 (1.1)	0 (0.0)	1 (1.7)	0 (0.0)
Insomnia	3 (4.7)	5 (8.1)	6 (10.0)	4 (4.4)	3 (5.0)	3 (5.0)	4 (4.5)
Ketonuria	5 (7.8)	6 (9.7)	4 (6.7)	9 (9.9)	9 (15.0)	6 (10.0)	9 (10.1)

Study N1539-02

This Phase II study was a randomized, double-blind, double-dummy, placebo-controlled, active-controlled, single center study in 230 subjects who underwent third molar extraction surgery. Subjects received a single dose of either IV placebo, oral ibuprofen 400 mg, or IV meloxicam 15 mg, 30 mg or 60 mg. Following dental surgery, subjects were dosed when their PI rating was moderate or severe on a 4-point Likert Scale (with categories of none, mild, moderate, or severe). Starting at the time of study drug administration and continuing for 24 hours thereafter, subjects were given access to rescue medication for pain not relieved by the study drug. Efficacy assessments were performed at the time of rescue medication administration and continued until the end of the 24-hour assessment period. SPID24 was the primary endpoint for this study. Subjects who received rescue medication prior to 24 hours had their PI scores recorded immediately prior to rescue and carried forward through 24 hours.

Overall, the results of this study consistently demonstrated that IV meloxicam produced the greatest reduction in pain, followed by the 30 mg and 15 mg doses as well as ibuprofen 400 mg. Highly statistically significant differences were seen among the treatments for the primary endpoint, SPID24 (Figure 3), as well as in every efficacy analysis.

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Figure 3: SPID24

The onset of action was rapid for the IV meloxicam doses, with statistically significant differences in PI and PR detected among the treatments as early as 10 minutes. For the IV meloxicam doses, analgesia was sustained, with statistically significant differences in PI and PR evident through 24 hours postdose. The PI differences by time point are presented in Figure 4.

Figure 4: Pain Intensity Differences for Each Time Point

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The use of rescue medication was reduced by 93%, 86%, and 87% by the IV meloxicam 60 mg, 30 mg, and 15 mg doses, respectively, compared to placebo.

Overall, treatment with IV meloxicam was well-tolerated after a single-dose up to 60 mg. There were no SAEs or discontinuations due to an adverse event, or AE, reported in this study. There were no clinically meaningful trends in vital signs or laboratory assessments. Adverse events were generally low and consistent with this surgical population (Table 2).

Table 2: Adverse Events Reported by more than 1 subject in any group

		Motrin	Meloxicam IV		
	Placebo n=30 n (%)	**400 mg n=50 n (%)**	**15 mg n=50 n (%)**	**30 mg n=50 n (%)**	**60 mg n=50 n (%)**
Nausea	1 (3.3)	1 (2.0)	1 (2.0)	0 (0.0)	3 (6.0)
Vomiting	0 (0.0)	2 (4.0)	1 (2.0)	0 (0.0)	2 (4.0)

Study N1539-05

This study was a Phase II, single-center, randomized, double-blind, placebo- and active-controlled, study conducted in subjects undergoing abdominal laparoscopic surgery. Allowed procedures included biliary tree surgery, common bile duct exploration/surgery, cholecystectomy, and inguinal hernia surgery. Subjects received either IV placebo; IV ketorolac every 6 hours; or IV meloxicam 7.5 mg every 12 hours, 15 mg every 12 hours, or 30 mg once daily, for up to 48 hours. Efficacy was assessed by subject reports of PI on a 100 mm VAS. Rescue medication was available any time after the initial dose of study drug. The study was expected to enroll 250 subjects. However, the prior sponsor decided to terminate this study for business reasons. A total of 50 subjects had been enrolled prior to the study discontinuation. Although a full efficacy analysis was not completed due to the early termination, analysis of the small set of subjects enrolled demonstrated that IV Meloxicam 30mg once daily produced a statistically significant difference compared to placebo for the SPID over 48 hours, or SPID48 (Figure 5).

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Figure 5: SPID48

Overall, study medication was well tolerated. The most frequently reported AEs for all subjects were headache, dry mouth, dysuria, nausea, fatigue, and dizziness. There was no apparent trend in occurrence of AEs and treatment group. SAE was reported by a subject in the ketorolac group. One subject in the IV meloxicam 7.5 mg every 12 hours group discontinued due to maculopapular rash.

Dexmedetomidine Overview

Dex is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Dex was developed in the 1990s by Abbott, initially for an indication as a short term sedative in the intensive care setting; however, a subsequent indication included use as a procedural sedative. Hospira currently markets IV Dex trademarked Precedex® in the United States. Orion received European approval to market IV Dex as an ICU sedative in the European Union, trademarked as Dexdor®. Dex has an extensive history of safe intravenous use, utilizing its sedative properties. We have formulated Dex at a significantly lower dose (perhaps as low as $1/10^{th}$ for our intranasal product) than the currently recommended IV dosage levels. Based upon our lower dose, we have seen minimal sedation to date in our clinical trials while still demonstrating an analgesic effect. Because we are pursuing a 505(b)(2) regulatory strategy, we have the ability to reference and access the patient data from the IV registration studies in 4,765 Dex-treated patients conducted in connection with these approvals in support of our filings.

We initially studied Dex-IN for the treatment of post-operative pain. In our completed Phase II trial, REC-14-013, Dex-IN met the primary endpoint of the clinical trial in demonstrating significant pain relief compared with placebo over 48 hours (p=0.0214). In October 2015 we met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program,

we believe that such a program is not advisable due to time, cost and associated risk. We plan to reevaluate Dex-IN as discussed with the FDA and intend to pursue a Phase II program in peri-procedural pain. If approved, Dex-IN would also be the first and only approved peri-procedural pain drug in its class of drugs.

Dex-IN Advantages

We believe there is a clear unmet need for effective, well tolerated, non-opioid analgesics that can be used as a component of an effective peri-procedural pain management program. Based on the safety profile and labeling for the marketed Dex product, we believe Dex has the potential to offer the following advantages:

Dex has demonstrated anxiolytic, or anxiety-reducing, properties. In the NDA studies for Dex it was demonstrated that Dex is a drug that also has anxiolytic properties. Patients experiencing pain typically see an increase in anxiety. We believe Dex s ability to help lessen anxiety will be beneficial in the peri-procedural setting.

Dex is not associated with constipation, nausea, or vomiting. Dex s mechanism of action provides analgesic activity with very limited activity on the gastrointestinal tract thus limiting the unwanted side effects of constipation, nausea and vomiting.

Dex does not cause respiratory depression. We believe that medical practitioners are highly concerned with respiratory depression, which is a well-documented side effect of opioid use (all opioids including fentanyl and oxycodone). Respiratory depression is defined by decreased lung ventilation leading to increased carbon dioxide and can be life threatening. Dex has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Dex is not considered a controlled substance. Opioid therapeutics are currently controlled by the DEA under the Controlled Substances Act. Under this act, opioids have been scheduled based on their potential for abuse and/or addiction. For those opioids placed in Schedule II, federal law prohibits the refilling of prescriptions, thus requiring patients to request and physicians to write additional prescriptions for each refill. Examples of Schedule II opioids include codeine, fentanyl, sufentanil, hydrocodone and oxycodone.

Dex has not demonstrated habituative effects. Preclinical studies in monkeys and rats have showed that Dex has a weak potential for drug addiction and dependence.

Patients utilizing Dex have been observed to be cognitively intact. We believe that patients utilizing opioid analgesics become cognitively impaired, impacting the patient s ability to perform routine mental and physical tasks. Based upon published studies, patients utilizing Dex do not appear to experience cognitive impairment.

Clinical Trial Overview

Under our investigational new drug applications, or INDs, we have studied various dosage forms of Dex in nine completed studies, including two Phase Ib and one Phase II placebo controlled studies, in over 200 subjects to evaluate the analgesic efficacy, safety and pharmacokinetics of Dex. After an interim analysis in September 2014, we closed our Post Op Day 0 Phase II clinical trial of Dex-IN in the treatment of acute post-operative pain following bunionectomy surgery. While the trial was not expected to reach statistical significance, a trend toward analgesia was observed in a subset of patients. In our completed second Phase II trial, REC-14-013, Dex-IN met the primary endpoint of the clinical trial in demonstrating significant pain relief compared with placebo over 48 hours ($p=0.0214$). Based upon the results of these trials, we believe that our formulations of Dex have demonstrated analgesic potential for moderate to severe pain. In October 2015 we met with the FDA to obtain feedback on the Phase II efficacy and

safety data, and for our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we believe that such a program is not advisable due to time, cost and associated risk. We plan to reevaluate Dex-IN as discussed with the FDA and intend to pursue a Phase II program in peri-procedural pain.

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REC-14-013

Our most recent completed Phase II study utilized Dex-IN initiating dosing of study medication on Post Op Day 1 following bunionectomy surgery. The Phase II trial was a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN in adult subjects undergoing bunionectomy surgery. Subjects were randomized to either a 50mcg dose of Dex-IN or a placebo intranasal dose given every 6 hours. Following the beginning of treatment, subjects remained under observation for 48 hours at study centers. Subjects 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 subjects were enrolled in the study. The key subject characteristics are listed in Table 3 below. One subject discontinued as a result of 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 SPID48, starting treatment on Post Op Day 1, utilizing the last observation carried forward (LOCF) analysis method. Dex-IN met the primary endpoint of the clinical trial in demonstrating significant pain relief compared with placebo over 48 hours (p=0.0214).

In general, DEX-IN was well tolerated. The most frequently reported adverse events reported in the Dex-IN group from the REC-14-013 trial are summarized in Table 4 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)

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No patients with blood pressure decrease, hypotension nor with bradycardia required medication to treat these events.

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

REC-13-012

This Phase II trial was a randomized, multicenter double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN, in adult subjects undergoing bunionectomy surgery with treatment beginning on Post Op Day 0. While analgesia and a reduction in opioid use were observed in a subset of patients at the planned interim analysis, we elected to discontinue the study as it was not expected to reach statistical significance. In this study, Dex-IN was well tolerated with no serious adverse events reported. Four subjects discontinued due to symptomatic hypotension and one subject discontinued due to fever. Additionally, one subject discontinued placebo due to nausea and vomiting.

No other adverse events of symptomatic hypotension were seen in the 95 patients treated. Asymptomatic decreases in blood pressure were seen throughout the study, including 10 Dex-IN patients that had an adverse event of BP decreased. In addition, one patient in the Dex-IN 50 mcg treatment group and two patients in the placebo treatment group had a heart rate of 50 bpm or below along with a notable change from baseline heart rate. Lastly, no clinically significant changes were seen in electrocardiograms in any treatment group, and there were no clinically significant changes in clinical laboratory studies.

Fadolmidine Overview

Our third product candidate under development, Fado, also belongs to the alpha-2 adrenergic agonist receptor class. Fado is similar to Dex and different from clonidine in that it is a full agonist of all subtypes of alpha-2 adrenoreceptor. Unlike Dex, Fado does not cross the blood brain barrier and this accounts for the targeting of Fado use for either intrathecal administration for pain or anesthesia, or potentially for topical use to treat pain associated with regional nerve pain from underlying nerve damage, also called neuropathies. Various preclinical models of pain have been employed and have demonstrated Fado s potential as an analgesic, including its potential for use in neuropathies and post-operative pain.

Fadolmidine Clinical Trials

In Orion sponsored studies, the safety and efficacy of Fado had been assessed in one Phase I study and in one Phase II study. In these studies, altogether 130 subjects received Fado. The Phase II study was a randomized, single blind, controlled, dose-escalation study. The aim of the study was to assess the safety, tolerability and efficacy of Fado when administered intrathecally with bupivacaine to induce spinal anesthesia in subjects undergoing bunionectomy surgery. Fado doses of 40, 60, 80, 100, 120, 140, 160, 180, 200, 220 and 240 mcg were administered with 5 mg of bupivacaine. At each dose level six subjects were randomized to receive combination treatment, and one subject to receive only isobaric bupivacaine 10 mg. In this study, Fado was shown to have beneficial effects. The time to first post-operative dose of rescue drug (patient controlled mini doses of morphine, called PCA) was longer with increasing Fado dose while total morphine use in the first ten hours was reduced. The subjects not only used less morphine, they also reported less pain. All doses of Fado appeared to delay the onset of pain while doses of Fado greater than 120 mcg also appeared to suppress pain.

Fado was well tolerated by subjects. Incontinence and bradycardia were observed only at the highest dose studied. The incidence of nausea and vomiting was higher on Fado compared to bupivacaine 10 mg alone, despite the reduction in intravenous morphine administered. Sedation did not appear to be increased on Fado. There were significant reductions in blood pressure after intrathecal Fado was added to bupivacaine. These reductions were dose-dependent.

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Contract Manufacturing Overview

We currently own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receive royalties associated with the sales of these products. This facility has been inspected by U.S., EU, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®. In each case, we either purchase active drug product from third parties or receive it from our commercial partners to formulate product using our technologies. The manufacture of these products for clinical trials and commercial use is subject to cGMPs and other regulatory agency regulations. Our manufacturing and development capabilities include formulation through process development, scale-up and full-scale commercial manufacturing and specialized capabilities for the development and manufacturing of controlled substances.

Although some materials for our products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We do not currently have any significant issues in finding suppliers. However, there is no certainty that we will be able to obtain long-term supplies of our manufacturing materials in the future.

Permits and Regulatory Approvals

We hold various licenses for our Gainesville manufacturing activities. The primary licenses held are FDA Registrations of Drug Establishments and DEA Controlled Substance Registration. Due to certain U.S. state law requirements, we also hold certain state licenses for distribution activities throughout certain states.

We do not generally act as the product authorization holder for products that have been developed on behalf of a commercial partner. In such cases, our commercial partner typically holds the relevant authorization from the FDA or other national regulator, and we support this authorization by furnishing a copy of the Drug Master File, or the chemistry, manufacturing and controls data to the relevant regulator to prove adequate manufacturing data in respect of the product. We generally update this information annually with the relevant regulator.

Material Commercial Supply Agreements

Actavis

Pursuant to an amended and restated license and supply agreement, or the License and Supply Agreement, between us and Watson Laboratories, Inc., or Watson, a subsidiary of Actavis plc, we exclusively manufacture generic Verapamil for Watson. We receive a percentage profit share from Watson on all U.S. sales of Verapamil and are compensated for manufacturing the product at cost (or, where product is supplied in finished form, at manufacturing cost plus a mark-up). Watson represented 30.2% of our revenues for the nine months ended September 30, 2015.

Under the License and Supply Agreement, we also license certain intellectual property to Watson and maintain the regulatory approval that is necessary to enable Watson to distribute Verapamil in the United States. Watson is responsible for distributing, marketing and promoting Verapamil in the United States. The License and Supply Agreement also contains certain restrictions in respect of manufacturing and selling competing products, although we are permitted to sell a branded version of Verapamil through a third party under the trade name Verelan®.

Either party may terminate the License and Supply Agreement on an annual basis by serving the other with a written notice of termination 90 days prior to the contract anniversary date. Each party may also terminate the License and

Supply Agreement in certain specified circumstances, including where their rates of return fall below certain specified thresholds. Watson can terminate the amended and restated license and supply agreement

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if we commit certain material breaches of contract, including failure to supply. If Watson exercises this right, then Watson may elect to obtain a production license from us. In all other circumstances, we retain the right to use all technical and clinical data that has been generated under the License and Supply Agreement upon its termination.

Intellectual Property

We own and license patents and patent applications directed to the sale, use, manufacturing, and formulating of IV/IM meloxicam. The patent protection for IV/IM meloxicam could lead to protection of IV/IM meloxicam through 2030, subject to any extensions or disclaimers. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act when applicable. The extensions under U.S. law may extend patent protection beyond 2030.

We own patents and patent applications directed to the composition of, manufacturing of, and formulating of Zohydro ER. The patent protection for Zohydro ER could provide for protection of Zohydro ER through 2034, subject to any extensions or disclaimers. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act when applicable. The extensions under U.S. law may extend patent protection beyond 2034.

We hold patent applications directed to the analgesia indication and formulations of Dex and we are progressing through the patent application process globally. We believe that the combination of the unique indication and formulations as well as the significant dosing differences with the routes of administration will allow us to, with the applications filed, protect our products from other Dex entrants to the analgesia field, regardless of formulation. Our strategy, if successful in obtaining patent protection, could lead to protection of our product candidates through 2030 subject to any extensions or disclaimers. The term may be extended due to patent term adjustment as a result of delays by the U.S. Patent and Trademark Office in issuing any patent. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act when applicable. The extensions under U.S. law may extend patent protection beyond 2030.

While our current focus is on seeking FDA approval for IV meloxicam for the treatment of moderate to severe pain, we also have in development proprietary drug solutions for peri-procedural pain and pain resulting from cancer, musculoskeletal disorders, and peripheral neuropathy. One goal is to leverage our drug development expertise along with innovative delivery systems to optimize absorption, improve effectiveness, and reduce side effects to optimize pain relief and improve quality of life for the millions of people suffering from moderate-to-severe pain annually. We have multiple delivery systems in development, including intrathecal/epidural, topical, transdermal, intranasal, and sublingual platforms.

Intellectual Property Protection

We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements to protect our product candidates. Our patent strategy is designed to facilitate commercialization of our current product candidates and future product candidates, as well as create barriers to entry for third parties. One focus of our claim strategy is on formulation claims and method of treatment claims.

We are seeking patent protection in the United States and internationally for our product candidates. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. We also intend to rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties.

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Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for our product candidates;
- defend our patents;
- develop trade secrets as needed and preserve the confidentiality of our trade secrets; and
- operate our business without infringing the patents and proprietary rights of third parties.

We have taken steps to build and will continue to build proprietary positions for our product candidates and related technology in the United States and abroad.

As a result of the Gainesville Transaction, we are now the owners of patents (U.S. Patent Nos.: 6,228,398, 6,902,742 and 9,132,096) relating to Zohydro-ER, which we license to our commercial partners, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States. These patents have expiration dates of November 1, 2019, November 1, 2019, and September 12, 2034, respectively. We also own a Canadian patent applications that are still pending relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. We cannot predict if the Canadian patent application will ever issue as a patent. We own patent applications and patents directed to nanoparticulate formulations of meloxicam that we expect to provide protection for IV/IM meloxicam, if IV/IM meloxicam gains marketing approval. The issued patents and any patents that may issue from various applications related to IV/IM meloxicam expire between 2016 and 2024 depending upon the application and patent.

Additionally, as part of the Gainesville Transaction we acquired ownership of various controlled release formulation patents including patents in the United States, Canada, and Europe. These patents are scheduled to expire between 2019 and 2026.

We have in-licensed the Orion patent rights to Dex and Fado in the United States and internationally. For Dex, the composition of matter patent (U.S. Patent No. 4,910,214) expired in mid-January 2014. For Fado, the composition of matter patent (U.S. Patent No. 6,313,311) expires on October 2, 2016 with a possible patent term extension under the Hatch-Waxman Act. Also for Fado, we have a pro-drug patent (U.S. Patent No. 7,759,496) that expires on April 10, 2025. If no additional patent protection is obtained, these patent expirations will impact our ability to prevent third parties from marketing generic equivalents. We have also licensed additional method of use patents for both Dex and Fado from Orion. We are also pursuing patent protection for the specific formulations, dosage forms and methods of use of our product candidates.

Our Dex patent portfolio comprises three families of patent applications. A family (U.S. Application Serial No. 12/781,628; which was also filed as a PCT Application, International Application No. PCT/US10/35136) provides, among other things, methods of treating or preventing pain by administering to the oral mucosa of a mammal. The active ingredient, or salt, can be used to treat or prevent pain without significant sedation. The first family also provides, among other things, oral, transmucosal, analgesic pharmaceutical compositions comprising an oral, transmucosal pharmaceutically effective amount of the active ingredient, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable vehicle. The pharmaceutically effective amount of the active ingredient treats or prevents pain without significant sedation. The first family also provides oral transmucosal dispensing

devices comprising the analgesic pharmaceutical composition.

Another family (U.S. Application Serial No. 13/711,407; which was also filed as a PCT application, International Application No. PCT/US12/68988) provides, among other things, methods of treating or preventing pain by intranasally administering an intranasally effective amount of the active ingredient. This family also provides metered dose devices comprising a pharmaceutical composition comprising the active ingredient, or salt thereof. The metered dose devices can deliver a metered dose spray of the pharmaceutical composition intranasally that is analgesic in a mammal.

The Dex patent applications are in various stages of prosecution, and no patent has been issued to date in the United States. Unless and until our pending applications issue, their protective scope is impossible to determine.

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Further, there is only one patent application in connection with our lead candidate, Dex-IN, which is also relatively early in the review process, which may take months or years, and there is no guarantee that the patent will issue. It is impossible to predict whether or how many of these applications will result in issued patents and patents that issue may be challenged in the courts or patent offices in the United States and abroad.

For the patent family regarding oral transmucosal Dex, if embodiments from the specification and/or present claims issued, the claims may cover: methods of treating or preventing pain without significant sedation via delivery of Dex to the oral mucosa; oral, transmucosal analgesic pharmaceutical compositions comprising Dex; and oral transmucosal dispensing devices containing Dex. For the patent family regarding Dex-IN, if embodiments from the specification and/or present claims issued, the claims may cover: methods of treating or preventing pain without significant sedation via delivering Dex intranasally; intranasal compositions comprising Dex; and/or metered dose devices containing Dex.

If these patent applications are issued as patents, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, the resulting patent protection in the United States may last into 2030, subject to any disclaimers or extensions. We note that the patent laws of foreign countries differ from those in United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

In-Licensing Arrangements

Alkermes plc

As part of the Gainesville Transaction, we in-licensed, on a perpetual, royalty-free basis, technology relating to IV/IM meloxicam, from Alkermes. We have also licensed patents and applications relating to the formulations and manufacturing of IV/IM meloxicam, including the NanoCrystal™ technology. These patent applications are scheduled to expire between 2015 and 2030.

Orion Corporation

Dexmedetomidine (Dex) License

In August 2008, we entered into an exclusive license with Orion for the development and commercialization of Dex for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, in the Territory. We have the right to sublicense the rights under this license at any time.

In consideration for this license, we are required to pay Orion lump sum payments on the achievement of certain developmental milestones and upon the achievement of certain commercial milestones. We will pay milestone payments to Orion of up to 20.5 million Euros ($23.0 million as of September 30, 2015) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. Although we have a separate agreement for the license of Dex in Japan that provides for separate development and commercial milestones, we expect that development of Dex for Japan will require a local partner that would be required to make sure milestone payments are made. We are also required to pay Orion a royalty on net sales that, during the term, generally varies from 10% to 20% depending on annual sales levels, and in some circumstances, such as in the event of the marketing of a generic competitor or a competing product being released by Orion or its licensees, could drop to low single digits, so long as Orion is not engaged in the use, manufacturing and/or commercialization of a pharmaceutical product containing Dex, medetomidine or detomidine as a therapeutically active ingredient for treatment of pain in humans in a Licensed

Dosage Form. Our royalty payments on net sales of Dex will be paid at varying percentages. Through September 30, 2015, no such milestones have been achieved.

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We are entitled to reference all regulatory filings made by Orion related to Dex, Dex products or the Dex active pharmaceutical ingredient, or API. Orion retained the rights to develop and commercialize Dex for all uses and indications other than pain in humans and for use in combination products in that field, and we have granted Orion a license to use our clinical trial data, patents and know-how for such purpose; provided, however that Orion cannot undertake development activities in the United States, Australia or South Africa with respect to treatment of pain in humans in any Licensed Dosage Form until four years after our first product is granted regulatory approval in the United States.

We have a right of first refusal to commercialize any such product developed by Orion in the Territory.

The initial term of this license is 15 years from the first commercial sale in the Territory. After the initial term, this license will be automatically extended for one or more periods of two years, unless either party provides written notice of termination at least six months prior to expiration. Each party has the right to terminate the agreement in connection with the bankruptcy, liquidation, or dissolution of the other party or for a material breach that is uncured or without a reasonably acceptable plan to cure such breach within 90 days. In the event of termination, inventions created by Orion will remain Orion s property and inventions created by us will remain our property. In the event that inventions are jointly created, the inventions will be the joint property of the parties.

Fadolmidine (Fado) License

In July 2010, we entered into an exclusive license agreement with Orion for the development and commercialization of Fado for use as a human therapeutic, in any dosage form in the Territory. We have the right to sublicense the rights under such license at any time.

In consideration for this license, we paid Orion an upfront payment and are required to pay certain lump-sum amounts on completion of certain development milestones, as well as on achievement of certain commercial milestones. We will pay milestone payments to Orion of up to 12.2 million Euros ($13.7 million as of September 30, 2015) based on regulatory filings and approval and on commercialized net sales levels. We will also pay Orion royalty payments on net sales of Fado ranging from 10% to 15%, so long as Orion is not engaged in the manufacture, use or sale of a competitive product containing Fado as a therapeutically active ingredient for treatment of human subjects, in the Territory, as defined in such agreement. Through September 30, 2015, no such milestones have been achieved.

We are entitled to reference data as well as information in prior Orion regulatory filings (European Union/Finland) made by Orion related to Fado. Orion retained the rights to develop and commercialize Fado in the European Union, the CIS and Turkey subject to the terms and conditions of the license agreement. In addition, Orion is entitled to receive a license-back to any intellectual property and data developed by us and, in the event Orion sublicenses the use of such intellectual property and data, Orion would be required to pay us a portion of our costs incurred in developing Fado. In the event of termination, inventions created by Orion will remain Orion s property and inventions created by us will remain our property. In the event that inventions are jointly created, the inventions will be the joint property of the parties.

The term of the license agreement is 15 years from the first commercial sale of a product by us in any country in the Territory, as defined in such agreement. After the initial term, the license agreement will be automatically extended on the same terms and conditions for one or more successive three year periods, unless either party provides written notice six months prior to the expiration of the initial term or any renewal term.

Each party has the right to terminate the agreement in connection with the bankruptcy, liquidation, or dissolution of the other party, for a material breach that is uncured or for which a reasonably acceptable plan to cure such breach has

not been developed within 90 days of receipt of written notice, upon our failure to develop and commercialize Fado as determined by Orion, which failure remains uncured or for which a reasonably acceptable plan to cure such failure has not been developed within 90 days of receipt of written notice, or if we or our licensees contest the Orion patent rights.

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Sales and Marketing

Our current intent is to develop and commercialize our product candidates in the United States while out-licensing development and commercialization rights for other territories outside the United States for which we own the territorial rights. We believe the initial target audience for our product candidates will be specialty physicians, including surgeons, anesthesiologists, and pain specialists. Our management team has experience building and launching therapeutics to specialty physicians. As this target audience is smaller than general practitioners, we believe we have the capabilities to build a sales and marketing infrastructure and effectively market our product candidates upon commercial approval. While our stated intention is to develop and commercialize our product candidates, we will evaluate potential strategic collaborations that could accelerate or enhance our development and, upon approval, commercial success of our product candidates.

Pharmaceutical Manufacturing and Supply

The source for Dex is Orion s Fermion Chemical Division, and the source for bulk IV/IM meloxicam formulation is Alkermes. We currently rely on contract manufacturers to produce drug product for IV/IM meloxicam, Dex and Fado for our clinical studies cGMPs, with oversight by our internal managers. Certain equipment specific to the pharmaceutical manufacturing process is leased by us and we are evaluating plans for commercial filling. We plan to continue to rely on contract manufacturers to manufacture development quantities of our product candidates, as well as commercial quantities of our product candidates, if and when approved for marketing by the FDA. We currently rely on a single manufacturer for the clinical supplies of our drug product for each of our product candidates and do not currently have agreements in place for redundant supply or a second source for any of our product candidates. We have identified other drug product manufacturers that could satisfy our clinical study requirements but this would require significant expense and could produce a significant delay in setting up the facility and moving equipment. Additionally, should a supplier or a manufacturer on whom we rely to produce a product candidate provide us with a faulty product or a product that is later recalled, we would likely experience significant delays and material additional costs.

Material Supply Agreements

Meloxicam

We are party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will (i) provide clinical and commercial bulk supplies of IV/IM meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for IV/IM meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk IV/IM meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV/IM meloxicam, subject to a maximum of eight clinical batches in any twelve-month period unless otherwise agreed by the parties. During the term of the Supply Agreement, we will purchase our clinical and commercial supplies of bulk IV/IM meloxicam formulation exclusively from Alkermes for a period of time. Sterile fill-finish of Meloxicam will be completed by a third party fill-finish facility. If the first commercial sale of meloxicam occurs on or prior to December 31, 2020, the Supply Agreement will have an initial term expiring ten years following the date of such first commercial sale. The Supply Agreement will then automatically renew for successive one-year terms unless terminated by either party upon written notice at least 180 days prior to the expiration of the applicable term. If the first commercial sale of Meloxicam has not occurred by December 31, 2020, the Supply Agreement will expire on that date.

The Supply Agreement may be terminated earlier (i) by us upon 180 days written notice following the date of first generic entry; (ii) by either party upon twelve months written notice following the first anniversary of the approval of the NDA for meloxicam; (iii) by either party upon written notice to the other party in the event of uncured material breach of the other party; and (iv) by Alkermes upon written notice in certain events of uncured non-payment.

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Dex API

We and Orion are parties to a separate API agreement, whereby Orion agrees to provide us API for the development and commercialization of the Dex and Fado product candidates.

During the development period prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed upon amounts. Any amounts ordered by us that are greater than the planned supply will be charged at 50% of the supply price for commercial product. We have agreed with Orion on the specifications for the cGMP for API and the stability testing, storage, handling and agreed quality of the API, as well as a dispute resolution process, should differences arise in interpretation of data for the API.

The terms for commercial supply of Dex API by Orion are subject to regulatory approval. The initial term of the agreement is the later of 15 years from the first commercial sale and 15 years after the effective date of the agreement, and in each case, will be automatically extended for one or more periods of two years unless terminated. After the initial term, the agreement may be terminated upon six months notice to the other party.

Device Manufacturing and Supply

The single unit dose intranasal sprayer for Dex is manufactured by a supplier of proprietary components and devices, and equipment is leased from the device supplier for filling at a contract manufacturer. It is possible that we will continue with this arrangement through clinical development, or may evaluate the option of entering a manufacturing agreement with the device originator, or evaluate alternative devices prior to commercialization. Suppliers of components, subassemblies and other materials are located in Europe, Asia, and the United States. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the Dex system. FDA regulations require that materials be produced under cGMPs or Quality Systems Regulation.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our current and future competitors include pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates or any other products that we may develop which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

In the post-operative pain relief setting, we believe patients are prescribed acetaminophen, NSAIDs, sodium channel blockers and opioids, depending on the severity of pain. Specifically, acetaminophen, NSAIDs and sodium channel blockers, we believe, are prescribed for mild to moderate pain relief, whereas we believe opioids are prescribed for

moderate to severe pain relief. While we will compete with all of these compounds in the post-operative pain setting, we believe IV/IM meloxicam will be prescribed for moderate to severe pain, competing with opioids and other non-opioid pain treatments. There are a number of pharmaceutical companies that

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currently market therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Endo Pharmaceuticals, Inc., Mallinckrodt plc, Depomed, Inc. and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors in the manufacture, marketing and commercialization of opioid therapeutics. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker. As far as potential competitors in development, we are not aware of any other alpha-2 agonists compounds in development for post-operative pain relief. However, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., Heron Therapeutics, Inc., Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

In cancer breakthrough pain relief, we expect to compete against established companies, including Teva Pharmaceutical Industries, Ltd., BioDelivery Sciences International, Inc., Kyowa Hakko, Insys Therapeutics, Inc. and Depomed, Inc. All of these potential competitors have various formulations of fentanyl, a fast-acting opioid. We are not aware of any non-fentanyl related therapeutics in development for the treatment of cancer breakthrough pain.

With our contract manufacturing facility, we compete with contract pharmaceutical manufacturing companies such as Catalent, Inc., Patheon Holdings Coöperatief U.A., and Adare Pharmaceuticals, Inc.

Government Regulation

Product Approval

Government authorities in the United States at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates, including our formulations of IV/IM meloxicam, Dex and Fado, must be approved by the FDA before they may legally be marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA s refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, corrective actions, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties or any other actions. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to the FDA s current Good Clinical Practices, or cGCPs, to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA for a new drug;

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satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and

FDA review and approval of the NDA.

The testing and approval process require substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase I. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.

Phase II. Phase II trials involve investigations in a limited patient population to identify possible AEs and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

Phase III. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can

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suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA s previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

The submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the FDA Amendments Act of 2007, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Section 505(b)(2) New Drug Applications. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA s prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the approved product on which the application relies that are listed in the FDA s publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed

patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product s listed patent or that such

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patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug s five year exclusivity period and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the patent application is otherwise approvable.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

We are pursuing a regulatory strategy pursuant to Section 505(b)(2) in connection with our NDA submissions for Dex-IN based on the expiration of the originator s patent. In the NDA submissions for our other product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize their commercial opportunities.

FDA Review of New Drug Applications. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product s identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and

under what conditions. An advisory

committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug s safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for patents that issue from some of our currently owned or licensed patents or patent applications to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient, or active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, the FDCA will not prevent the submission or approval of another full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate,

well-controlled clinical trials to demonstrate safety and effectiveness. Further, a Section 505(b)(2) application may be submitted after four years if it contains a

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Paragraph IV certification that a listed patent is invalid, unenforceable, or not infringed for the applicant s drug product. The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under a Section 505(b)(2) NDA or an ANDA for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of an ANDA or a Section 505(b)(2) NDA product that did not incorporate the exclusivity-protected changes of the approved drug product. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug or competitive product.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached to any existing exclusivity (e.g., three or five year exclusivity) or patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued Written Request for such a trial. The current pediatric exclusivity provision was reauthorized in September 2007.

Post-Approval Requirements

Any drugs for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the FDA Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are required to list their products and to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our site or at the facilities of our

contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

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The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

The Drug Enforcement Administration.

Certain products that we manufacture are regulated as a controlled substance as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control and handling of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients are listed by the DEA as Schedule II and Schedule III under the CSA. Consequently, their manufacture, shipment and storage are subject to a high degree of oversight and regulation. The DEA establishes annually an aggregate quota for how much certain controlled substances that we manufacture may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA requires facilities that manufacture controlled substances to maintain certain security requirements. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports made to the DEA, for example, distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

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There is a risk that DEA regulations may interfere with the manufacture and supply of the drugs sold commercially, and thus on our ability to produce products in the volume needed to meet commercial demand.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Third Party Payor Coverage and Reimbursement

In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. As required by Medicare contracting reform, CMS is transitioning from fiscal intermediaries and carriers to Medicare Administrative Contractors for fee-for-service Medicare. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare

practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care

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Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Health Care Reform Law, which require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;

the federal Health Information Technology for Economic and Clinical Health Act, which made changes to HIPAA including extending the reach of HIPAA beyond HIPAA covered entities, increased the maximum civil monetary penalties for violations of HIPAA, granted enforcement authority to state attorneys general, and imposed a breach notification requirement on HIPAA covered entities and business associates; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial

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insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Employees

We currently have 14 full-time employees based in our corporate headquarters and 160 full-time employees and 1 part-time employee in Gainesville. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

Facilities

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 4,000 square feet of laboratory and office space. We have an office services agreement with Malvern Consulting Group, or MCG, a consulting company affiliated with our Chief Executive Officer, which includes the use of space as well as the use of certain equipment and access to certain administrative services (for example, telephones, copy machines, and kitchen facilities). We believe that this agreement is on arm s length terms and is adequate for our current needs. The agreement is on a quarter to quarter basis.

We own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products.

Legal Proceedings

As part of the Gainesville Transaction, we acquired the rights to Zohydro ER, which we license to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER is subject to five paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER, one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA, another two of which were filed in November 2015 by Actavis and in December 2015 by Alvogen regarding newly listed patent U.S. Patent No. 9,132,096. These certification notices allege that the three U.S. patents listed in the FDA s Orange Book for Zohydro ER, with an expiration date in November 2019 or September 2034, will not be infringed by Actavis or Alvogen s proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and our predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and in 2015 we filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In addition, in April 2015, the U.S. Patent and Trademark Office declared an interference between our U.S. Patent Application No. 11/372,857 relating to Zohydro ER, or the 857 application, and two Purdue Pharma, LP, or Purdue, applications.

Under our license agreement with Pernix, we have the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant, and Pernix has the obligation to reimburse us for all reasonable costs of such actions. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER and prosecute the 857 patent, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation or interference.

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DESCRIPTION OF OUR CAPITAL STOCK

The following description of our capital stock and provisions of our articles of incorporation, bylaws and the Pennsylvania Business Corporation law are summaries and are qualified in their entirety by reference to the articles of incorporation and the bylaws.

Pursuant to our Second Amended and Restated Articles of Incorporation, our authorized capital stock consists of 50,000,000 shares of common stock, par value of $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share, to be designated from time to time by our board.

Common Stock

As of December 22, 2015, there were 9,224,315 shares of our common stock issued and outstanding. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock in person or represented by proxies in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock that we may issue may be entitled to elect.

Subject to preferences that may be applicable to any then-outstanding shares of preferred stock, holders of our common stock are entitled to receive ratable dividends when, as, and if declared by our board of directors out of funds legally available therefor, subject to any preferential dividend rights of outstanding preferred stock. In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to ratably receive the net assets of our company available after the payments of all debts and other liabilities and subject to the prior rights of the holders of any then-outstanding shares of preferred stock.

Holders of our common stock have no preemptive, subscription, redemption or conversion rights. All outstanding shares of our common stock are, and the common stock to be outstanding upon completion of this offering, will be, duly authorized, validly issued, fully paid and non-assessable. The rights and privileges of the holders of the common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors has the authority, without further action by our shareholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Common Stock Warrants

We issued to the representatives of the underwriters in our IPO warrants to purchase up to 150,000 shares of our common stock, with a per share exercise price equal to $12.00, or 150% of the public offering price, or IPO warrants. The IPO warrants provide for certain piggyback registration rights. The IPO warrants are exercisable by the underwriters at any time, in whole or in part, during the four year period commencing one year after the

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closing of our IPO. On July 22, 2015, we issued 2,941 shares of our common stock pursuant to a cashless exercise of 10,000 IPO warrants with a per share exercise price of $12.00 per share.

In connection with the Gainesville Transaction, we issued to Alkermes a seven-year warrant to purchase an aggregate of 350,000 shares of our common stock, with a per share exercise price of $19.46 per share. In addition, we issued to OrbiMed a seven year warrant to purchase an aggregate of 294,928 shares of our common stock, with a per share exercise price of $3.28 per share, subject to certain adjustments.

Registration Rights

Private Placement

In July 2015 we completed a private placement to certain investors of 1,379,311 shares of our common stock. In connection with the private placement, we entered into a securities purchase agreement, or Purchase Agreement, with such investors under which we granted the investors certain registration rights with respect to the shares purchased. In particular, the Purchase Agreement required us to file a registration statement with the SEC to register the sale of such shares within 45 days of the consummation of the private placement. A registration statement relating to such shares was filed on August 20, 2015 and declared effective by the SEC on September 1, 2015.

IPO Warrants

As stated above, holders of the IPO warrants have certain piggyback registration rights. If at any time prior to the third anniversary of our IPO we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of the IPO warrants will be entitled to notice of the registration and the right to include the shares of common stock issuable upon exercise of their IPO warrants in the registration statement. If our proposed registration involves an underwriting, the underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares. The holders of IPO Warrants have waived their registration rights with regard to this prospectus.

Prior Holders of Series A Redeemable Convertible Preferred Stock

Holders of our common stock that were issued upon conversion of our Series A Redeemable Convertible Preferred Stock immediately prior to the closing of our IPO are entitled to the following rights with respect to the registration of such shares, or registrable securities, for public resale under the Securities Act, pursuant to an Investor Rights Agreement by and among us and certain of our shareholders. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights. If at any time the holders of a majority of the registrable securities request in writing that we file a registration statement under the Securities Act for the registration of at least 20% of our common stock then outstanding with an aggregate price of at least $20 million, we may be required to register their shares. We are obligated to effect no more than two registrations for the holders of registrable securities in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten on a pro rata basis for reasons related to the marketing of the shares.

Piggyback Registration Rights. If at any time we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the

registration and the right to include their shares of registrable securities in the registration statement. If our proposed registration involves an underwriting, the underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

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Form S-3 Registration Rights. If at any time we are entitled under the Securities Act to register our shares of common stock on Form S-3, holders of not less than 10% of the registrable securities then outstanding request in writing that we register their shares for public resale on Form S-3 and the reasonably anticipated price to the public is $10 million or more, we will be required to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if (1) we certify in a certificate signed by our Chief Executive Officer that we intend to engage in a registered public offering within 90 days of receiving the Form S-3 request, or (2) we certify in a certificate signed by our Chief Executive Officer stating that in our good faith judgment, it would be detrimental to us for such registration on Form S-3 to be effected at such time, in which event we have the right to defer the filing of the Form S-3 registration statement for a period of not more than 120 days.

Expenses. Subject to certain exceptions, and other than underwriting discounts and selling commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, blue sky fees and expenses and the expenses of any special audits incident to or required by the registration.

Termination of Registration Rights. These registration rights terminate on the third anniversary of our IPO. In addition, a holder s registration rights will expire if all registrable securities held by and issuable to such holder could be sold under Rule 144 of the Securities Act during any 90-day period.

Anti-Takeover Effects of Pennsylvania Law and Our Articles of Incorporation and Bylaws

Pennsylvania Anti-Takeover Law

Provisions of the Pennsylvania Business Corporation Law of 1988, or the PBCL, applicable to us provide, among other things, that:

- we may not engage in a business combination with an interested shareholder, generally defined as a holder of 20% of a corporation s voting stock, during the five-year period after the interested shareholder became such except under certain specified circumstances;

- holders of our common stock may object to a control transaction involving us (a control transaction is defined as the acquisition by a person or group of persons acting in concert of at least 20% of the outstanding voting stock of a corporation), and demand that they be paid a cash payment for the fair value of their shares from the controlling person or group ;

- holders of control shares will not be entitled to voting rights with respect to any shares in excess of specified thresholds, including 20% voting control, until the voting rights associated with such shares are restored by the affirmative vote of a majority of disinterested shares and the outstanding voting shares of the Company; and

- any profit, as defined, realized by any person or group who is or was a controlling person or group with respect to us from the disposition of any equity securities within 18 months after the person or

group became a controlling person or group shall belong to and be recoverable by us. Pennsylvania-chartered corporations may exempt themselves from these and other anti-takeover provisions. Our articles of incorporation do not provide for exemption from the applicability of these or other anti-takeover provisions in the PBCL.

The provisions noted above may have the effect of discouraging a future takeover attempt that is not approved by our board of directors but which individual shareholders may consider to be in their best interests or in which shareholders may receive a substantial premium for their shares over the then current market price. As a result, shareholders who might wish to participate in such a transaction may not have an opportunity to do so. The provisions may also result in making the removal of our board of directors or management more difficult.

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Furthermore, such provisions could render our company being deemed less attractive to a potential acquiror and/or could result in our shareholders receiving a lesser amount of consideration for their shares of our common stock than otherwise could have been available either in the market generally and/or in a takeover.

Articles of Incorporation and Bylaws

Provisions of our articles of incorporation and bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that our shareholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our articles of incorporation and bylaws:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Stock Market Listing

Our shares of common stock are listed for trading on the NASDAQ Capital Market under the symbol REPH.

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SELLING SHAREHOLDER

The selling shareholder may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the selling shareholder in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling shareholder s interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling shareholder for whom we are registering shares for sale to the public, the number of shares of common stock beneficially owned by the selling shareholder prior to this offering, the total number of shares of common stock that the selling shareholder may offer pursuant to this prospectus and the number of shares of common stock that the selling shareholder will beneficially own after this offering. Except as noted below, the selling shareholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling shareholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling shareholder, assuming that the selling shareholder sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling shareholder will not own any shares other than those appearing in the column entitled Beneficial Ownership After This Offering. We cannot advise you as to whether the selling shareholder will in fact sell any or all of such shares of common stock. In addition, the selling shareholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering(1)	
Name	**Shares of Common Stock Owned Prior to this Offering**	**Shares of Common Stock Being Offered**	**Number of Shares**	**%**
Aspire Capital Fund, LLC (2)	96,463(3)	2,500,000	0	0

(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling shareholder is under no obligation known to us to sell any shares of common stock at this time.

(2) Aspire Capital Partners LLC (Aspire Partners) is the Managing Member of Aspire Capital Fund LLC (Aspire Capital). SGM Holdings Corp (SGM) is the Managing Member of Aspire Partners. Mr. Steven G. Martin is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown is the president and sole shareholder of Red Cedar Capital Corp (Red Cedar), which is a principal of Aspire Partners. Mr. Christos Komissopoulos is president and sole shareholder of Chrisko Investors Inc. (Chrisko), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Capital. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial

ownership of the common stock held by Aspire Capital. Aspire Capital is not a licensed broker dealer nor is any of its affiliates a licensed broker dealer.

(3) As of the date hereof, 96,463 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of shares we issued to Aspire Capital as a commitment fee. We may elect in our sole discretion to sell to Aspire Capital up to an additional 2,403,537 shares under the Purchase Agreement and included in this prospectus but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

Certain Relationships and Related Party Transactions

See The Aspire Capital Transaction.

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PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Aspire Capital, the selling shareholder. The common stock may be sold or distributed from time to time by the selling shareholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

ordinary brokers transactions;

transactions involving cross or block trades;

through brokers, dealers, or underwriters who may act solely as agents;

at the market into an existing market for the common stock;

in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

in privately negotiated transactions; or

any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling shareholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling shareholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling shareholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an underwriter within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other shareholder, broker, dealer, underwriter, or agent

relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling shareholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than eight percent (8%) of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is

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unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling shareholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby in this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering has been passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania.

EXPERTS

The financial statements of Recro Pharma, Inc. as of December 31, 2013 and 2014, and for the years then ended have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The audited historical combined financial statements of DARA incorporated in this prospectus by reference to Recro Pharma, Inc. s Current Report on Form 8-K/A dated June 2, 2015 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

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INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 25, 2015;
- our Quarterly Reports on Form 10-Q for the periods ended March 31, 2015, June 30, 2015 and September 30, 2015, filed on May 12, 2015, August 14, 2015 and November 13, 2015, respectively;
- our Current Reports on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that are related to such items) filed on February 3, 2015, February 5, 2015, March 11, 2015, April 10, 2015, April 16, 2015 (as amended by Form 8-K/A filed on June 2, 2015, Form 8-K/A filed on June 26, 2015, Form 8-K/A filed on July 21, 2015 and Form 8-K/A filed on December 23, 2015), May 12, 2015, May 28, 2015, June 26, 2015, July 8, 2015, July 16, 2015, July 17, 2015, July 24, 2015, September 10, 2015, October 16, 2015 (as amended by Form 8-K/A filed on December 11, 2015), October 26, 2015, October 30, 2015, November 17, 2015, December 2, 2015, December 22, 2015 and December 23, 2015;
- The portions of our Definitive Proxy Statement on Schedule 14A filed on April 29, 2015 that are deemed filed with the SEC; and
- The description of our common stock contained in our registration statement on Form 8-A filed on March 4, 2014 (Registration no. 001-36329) with the SEC, including any amendment or report filed for the purpose of updating such description.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Susan Kim, Argot Partners, 767 Third Avenue, 29th Floor, New York, NY 10017, (212) 600-1902, email address:susan@argotpartners.com. In addition, copies of any or all of the documents incorporated herein by reference may be accessed at our website at http://www.recropharma.com. The information on such website is not incorporated by reference and is not a part of this prospectus.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC s public reference room at 100 F Street NE, Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the SEC s public reference facilities by calling the SEC at 1-800-SEC-0330. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC at its principal office at 100 F Street NE, Room 1580, Washington, D.C. 20549-1004. The SEC maintains an Internet website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our SEC filings are accessible through the Internet at that website. Our reports on Forms 10-K, 10-Q and 8-K, and amendments to those reports, are also available for download, free of charge, as soon as reasonably practicable after these reports are filed with the SEC, at our website at www.recropharma.com. The content contained in, or that can be accessed through, our website is not a part of this prospectus.

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2,500,000 Shares

Common Stock

PROSPECTUS

, 2015

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

Set forth below is an estimate (except in the case of the registration fee) of the amount of fees and expenses to be incurred in connection with the issuance and distribution of the offered securities registered hereby, other than underwriting discounts and commission, if any, incurred in connection with the sale of the offered securities. All such amounts will be borne by Recro Pharma, Inc.

	Amount to be paid
SEC registration fee	$ 1,100
Printing expenses	50,000
Accounting fees and expenses	30,000
Legal fees and expenses	75,000
Miscellaneous	20,000
Total	$ 176,100

Item 14. Indemnification of Directors and Officers.

The Company s by-laws provide that, to the fullest extent permitted by Pennsylvania law, any officer or director of the Company who was or is a party or is threatened to be made a party to, any threatened, or pending or completed action, suit or proceeding, whether civil, criminal, administrative, or investigative, by reason of fact that he/she is or was acting as a representative of the corporation, or is or was serving at the request or for the benefit of the Company as a director, officer, employee, agent, partner, or fiduciary of, or in any other capacity for, another corporation or any partnership, joint venture, trust, employee benefit plan or other enterprise, shall be indemnified by the Company for any losses or expenses incurred in connection with service as an officer or director of the Company, if the director or officer acted in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Company and, with respect to any criminal proceeding, had no reasonable cause to believe his conduct was unlawful.

Pennsylvania law requires that to the extent that a director or officer of the Company has been successful on the merits or otherwise in defense of any action or proceeding referred to above or in defense of any claim, issue or matter therein, that director or officer shall be indemnified against expenses (including attorney fees) actually and reasonably incurred by him in connection therewith. The Company s by-laws further provide that the right to indemnification includes the right to have expenses reasonably incurred in defending any action or proceeding described above paid by the Company in advance of the final disposition of the action or proceeding to the fullest extent permitted by Pennsylvania law; provided that, if required by Pennsylvania law, the payment of such expenses incurred in advance of the final disposition of the action or proceeding shall be made only upon delivery to the Company of an undertaking to repay all amounts so advanced without interest if it is ultimately determined that the director or officer is not entitled to be indemnified.

Indemnification shall not be made in respect of any claim, issue or matter as to which the person has been adjudged to be liable to the Company unless and only to the extent that a court determines that, despite the adjudication of liability

but in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for the expenses that the court deems proper. Nor shall indemnification be made in any case where the act or failure to act giving rise to the claim for indemnification is determined by a court to have constituted willful misconduct or recklessness.

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Item 15. Recent Sales of Unregistered Securities.

Private Placement

On July 7, 2015, the Company closed a Private Placement with certain accredited investors in which it sold 1,379,311 shares of common stock at a price per share of $11.60, for net proceeds of approximately $14.8 million. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the Private Placement, plus reimbursement of certain expenses. The shares of common stock sold in the Private Placement were sold in reliance on the exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. Each of the investors represented that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

Alkermes and Orbimed Warrants

On April 10, 2015, in connection with the closing of the Company s acquisition from Alkermes Pharma Ireland Limited (APIL) and pursuant to a Purchase and Sale Agreement dated March 7, 2015 (the Purchase and Sale Agreement), the Company issued to APIL a warrant to purchase 350,000 shares of the Company s common stock at an exercise price equal to $19.46 per share (the Alkermes Warrant). On April 10, 2015, the Company also issued to OrbiMed Royalty Opportunities II, LP (Orbimed), pursuant to the Company s Credit Agreement with Orbimed (the Credit Agreement), a warrant to purchase 294,928 shares of the Company s common stock at a price equal to $3.28 per share, subject to certain adjustments (the Orbimed Warrant, and together with the Alkermes Warrant, the Warrants).

The Warrants are exercisable until April 10, 2022. The number of shares for which the Warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the Warrants. The holders of the Warrants have the right to net exercise any outstanding Warrants for shares of common stock. As specified in each of the Warrants, upon a change of control of the Company, to the extent that the Warrants are not assumed by the acquiring entity or, in the case of the Orbimed Warrant, automatically exercised, the holder can elect to receive, subject to certain limitations and assumptions, cash equal to the Black-Scholes value of the outstanding Warrants.

The Company relied on the exemption from registration contained in Section 4(2) of the Securities Act, and Regulation D, Rule 506 thereunder, for the issuance of the Warrants and the shares of Common Stock issuable pursuant to such Warrants (the Warrant Shares). As part of executing the Purchase and Sale Agreement and the Credit Agreement and receiving the Warrants and the Warrant Shares, Orbimed and each of the Sellers each represented that it is an accredited investor as defined in Regulation D of the Securities Act and that the securities purchased by them will be acquired solely for their own account for investment and not with a view to or for sale or distribution of the Warrants or the Warrant Shares or any part thereof.

Aspire Capital Transaction

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, an Illinois limited liability company , or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company s common stock (the Purchase Shares) over the 24-month term of the Purchase Agreement.

Upon execution of the Purchase Agreement, the Company issued 96,463 shares of its common stock to Aspire Capital in consideration for entering into the Purchase Agreement. The Purchase Shares may be sold by the Company to Aspire Capital on any business day the Company selects in two ways: (1) through a regular purchase of up to 50,000

shares at a known price based on the market price of the Company s common stock prior to the time of each sale, and (2) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 95% of the volume weighted average price for such purchase date.

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The issuance of the Commitment Shares and all other shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act of 1933, as amended (the Securities Act), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

IPO Warrants

Upon the closing of the IPO, the Company issued to Aegis Capital Corporation, the representative of the underwriters for the IPO, warrants to purchase up to 150,000 shares of the Company s common stock, with a per share exercise price equal to $12.00, or 150% of the public offering price. The warrants are exercisable by the underwriters at any time, in whole or in part, until March 12, 2019. On July 22, 2015, the Company issued 2,941 shares of its common stock pursuant to a cashless exercise of 10,000 IPO warrants with a per share exercise price of $12.00 per share. The issuance of the IPO warrants and all other shares of common stock that have been and may be issued upon exercise of the IPO warrants is exempt from registration under the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

Conversion of Series A Redeemable Convertible Preferred Stock

Upon the closing of the IPO on March 12, 2014, all shares of the Company s then-outstanding Series A Redeemable Convertible Preferred Stock and all of the Company s then-outstanding 8% Convertible Promissory Notes automatically converted into an aggregate of 3,239,500 shares of common stock. The issuance qualified for exemption under Section 3(a)(9) of the Securities Act.

8% Convertible Promissory Notes

In each of calendar years 2012, 2013, and 2014, the Company sold an aggregate of $952,013, $660,101, and $131,183 respectively, of its 8% Convertible Promissory Notes in private placements to SCP Vitalife Partners II, L.P., and $317,987, $220,483, and $43,817, respectively, of its 8% Convertible Promissory Notes in private placements to SCP Vitalife Partners (Israel) II, L.P. The notes accrue interest at a rate of 8% compounded quarterly. The notes converted into shares of the Company s common stock at the IPO. The notes were issued to SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P. in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) of the Securities Act relative to transactions by an issuer not involving a public offering. All purchasers of the 8% Convertible Promissory Notes represented to the Company in connection with their purchase that they were accredited investors and were acquiring such notes for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Stock Option Grants

Through March 2014, prior to the Company s IPO and prior to the effectiveness of the Company s registration statement on Form S-8, the Company granted stock options under the 2008 Stock Option Plan and the 2013 Equity Incentive Plan to purchase an aggregate of 334,800 shares of the Company s common stock at a weighted-average exercise price of $6 per share to certain directors, employees and consultants. The stock options and the common stock issuable upon the exercise of such options were issued pursuant to written compensatory plans or arrangements with the Company s directors, employees and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set

forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access through the Company s employment or other relationships to such information.

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Item 16. Exhibits.

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Registration Statement on Form S-1, which Exhibit Index is incorporated herein by reference.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:
(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser: if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against

such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Malvern, Pennsylvania, on December 23, 2015.

RECRO PHARMA, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gerri A. Henwood Gerri A. Henwood	President, Chief Executive Officer and Director (Principal Executive Officer)	December 23, 2015
* Donna Nichols	Vice President, Corporate Controller (Principal Accounting Officer, performing the duties of Principal Financial Officer)	December 23, 2015
* Alfred Altomari	Director	December 23, 2015
* William L. Ashton	Director	December 23, 2015
* Michael Berelowitz	Director	December 23, 2015
* Winston J. Churchill	Director	December 23, 2015
* Karen Flynn	Director	December 23, 2015
*	Director	December 23, 2015

Abraham Ludomirski		
*	Director	December 23, 2015
Wayne B. Weisman		

* The undersigned by signing her name hereto signs and executes this Amendment No. 1 to Registration Statement on Form S-1 pursuant to the Powers of Attorney executed by the above named signatories and previously filed with the Securities and Exchange Commission on February 3, 2015 and filed herewith.

* By: /s/ Gerri A. Henwood
Gerri A. Henwood
Attorney-in-Fact

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EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
3.1	Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed on March 13, 2014.
3.2	Third Amended and Restated Bylaws of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K filed on March 13, 2014.
4.1	Specimen certificate evidencing shares of common stock.	Incorporated herein by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1/A filed on December 20, 2013.
4.2	Investor Rights Agreement, dated September 4, 2008, by and among Recro Pharma, Inc., and the investors party thereto.	Incorporated herein by reference to Exhibit 4.2 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
4.3	Registration Rights Agreement, dated February 2, 2015, between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed on February 3, 2015.
4.4	Form of Alkermes Warrant.	Incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed on March 11, 2015.
4.5	Form of OrbiMed Warrant.	Incorporated herein by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed on March 11, 2015.
5.1	Opinion of Ballard Spahr LLP.	Incorporated herein by reference to Exhibit 5.1 to the Company s Registration Statement on Form S-1 filed on February 3, 2015.
10.1	Dexmedetomidine License Agreement, dated August 22, 2008, by and among Recro Pharma, Inc. and Orion Corporation.	Incorporated herein by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.2	First Amendment to Dexmedetomidine License Agreement, dated January 17, 2009, by and between Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.3	Dexmedetomidine API Supply Agreement, dated August 22, 2008, by and among Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.4	Fadolmidine License Agreement, dated July 21, 2010, by and among Recro Pharma, Inc. and Orion	Incorporated herein by reference to Exhibit 10.4 to the Company s Registration Statement on Form

	Corporation.	S-1/A filed on November 29, 2013.
10.5	Employment Agreement, dated October 8, 2013, between Recro Pharma, Inc. and Gerri Henwood.	Incorporated herein by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.

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Exhibit No.	Description	Method of Filing
10.6	Separation and Mutual Release Agreement, dated December 8, 2015, between Recro Pharma, Inc. and Charles Garner.	Filed herewith.
10.7	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Randall Mack.	Incorporated herein by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.8	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Diane Myers.	Incorporated herein by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.9	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Donna Nichols.	Incorporated herein by reference to Exhibit 10.9 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.10	Form of Amendment to the Employment Agreement for each of Gerri Henwood, Charles Garner, Randall Mack, Diane Myers and Donna Nichols.	Incorporated herein by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed on December 19, 2014.
10.11	2008 Stock Option Plan.	Incorporated herein by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.12	Form of 2008 Stock Option Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.11 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.13	2013 Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 13, 2014.
10.14	Form of 2013 Equity Incentive Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.14 to the Company s Annual Report on Form 10-K filed on March 25, 2015.
10.15	Recro Pharma, Inc. Amended and Restated Equity Incentive Plan	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on June 26, 2015.
10.16	Form of Recro Pharma, Inc. Equity Incentive Plan Award Agreement Award Agreement for Restricted Stock Units.	Incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on December 22, 2015.
10.17	Form of Award Agreement for Inducement Awards.	Incorporated herein by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-8 filed on December 23, 2015.
10.18	Master Consulting Services Agreement, dated October 10, 2013, by and between Recro Pharma, Inc. and Malvern Consulting Group, Inc.	Incorporated herein by reference to Exhibit 10.14 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.

10.19	Office Services Agreement, dated January 1, 2012, between Recro Pharma, Inc. and Malvern Consulting Group, Inc.	Incorporated herein by reference to Exhibit 10.15 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.

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Exhibit No.	Description	Method of Filing
10.20	Amendment #1 to the Office Services Agreement, dated October 3, 2013, by and between Recro Pharma, Inc. and Malvern Consulting Group, Inc.	Incorporated herein by reference to Exhibit 10.16 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013.
10.21	Common Stock Purchase Agreement, dated February 2, 2015, between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on February 3, 2015.
10.22	Credit Agreement, dated as of March 7, 2015, by and between Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 11, 2015.
10.23	First Amendment to Credit Agreement, dated as of April 10, 2015, by and between Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on April 16, 2015.
10.24	Fifth Amendment to Credit Agreement, dated as of November 12, 2015, by and between Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q filed on November 13, 2015.
10.25	Guarantee, dated as of March 7, 2015, by Recro Pharma, Inc. in favor of OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on March 11, 2015.
10.26	Asset Transfer and License Agreement, dated as of April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.
10.27	Transition Services Agreement, dated as of April 10, 2015, by and among Alkermes Pharma Ireland Limited, Recro Pharma, Inc., DV Technology LLC, and Alkermes Gainesville LLC.	Incorporated herein by reference to Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.
10.28	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed on August 14, 2015
10.29	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed on August 14, 2015
10.30	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed on August 14, 2015

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Exhibit No.	Description	Method of Filing
10.31	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed on August 14, 2015
10.32	Form of Securities Purchase Agreement, dated July 1, 2015, by and among Recro Pharma, Inc. and the Purchasers party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on July 8, 2015
10.33	Employment Agreement, dated December 1, 2015, between Recro Pharma, Inc. and Stewart McCallum, M.D.	Filed herewith.
10.34	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on December 23, 2015
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	Filed herewith.
23.3	Consent of Ballard Spahr LLP (included in Exhibit 5.1).	Previously filed.
24.1	Power of Attorney.	Previously filed.
24.2	Power of Attorney.	Filed herewith.

Exhibit relates to compensation arrangements.
Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission.