Recro Pharma, Inc.
Form S-1/A
December 13, 2016
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As filed with the Securities and Exchange Commission December 12, 2016

Registration Statement No. 333-214856

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

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:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

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. ¨

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 ¨	Smaller Reporting Company þ
		(Do not check if a smaller reporting company)	

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.

Title of each class of securities to be registered	**Amount to be registered[1]**	**Proposed Maximum Offering Price Per Share[2]**	**Proposed Maximum Aggregate Offering Price[2]**	**Amount of Registration Fee[3]**
Common Stock, $0.01 par value per share	7,395,498	$6.22	$45,999,998	$5,332[3]

(1) Includes 964,630 shares which the underwriters have the option to purchase from the registrant.
(2) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.
(3) Previously paid.

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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The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject To Completion, Dated December 12, 2016

PRELIMINARY PROSPECTUS

6,430,868 Shares

RECRO PHARMA, INC.

Common Stock

Recro Pharma, Inc. is offering 6,430,868 shares of common stock. Trading Symbol: Nasdaq Capital Market REPH.

The last reported sale price for our common stock on the Nasdaq Capital Market on December 12, 2016 was $6.22 per share. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

We are an emerging growth company as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we are eligible for reduced public company reporting requirements. Please see Summary Implications of Being an Emerging Growth Company.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 11 of this prospectus and under similar headings in the documents incorporated by reference into this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds, before expenses, to us	$	$

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses, including expenses for which we have agreed to reimburse the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase an additional 964,630 shares of our common stock.

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

Delivery of the shares of common stock is expected to be made on or about , 2016.

Piper Jaffray

The date of this prospectus is , 2016.

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You should read this prospectus, including the information incorporated by reference herein, and any related free writing prospectus that we have authorized for use in connection with this offering.

You should rely only on the information that we have included or incorporated by reference in this prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. This prospectus and any related free writing prospectus 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 or any related free writing prospectus 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 or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference herein or therein is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading Where You Can Find More Information.

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SUMMARY

This summary highlights information contained in other parts of this prospectus and in the documents we incorporate by reference. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus, any applicable free writing prospectus and the documents incorporated by reference herein and therein. You should read all such documents carefully, especially the risk factors and our consolidated financial statements and the related notes included or incorporated by reference herein or therein, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to Recro, we, us and our refer to Recro Pharma, Inc. and our subsidiaries.

Overview

Company Overview

We are a revenue-generating, specialty pharmaceutical company primarily focused on developing innovative products for hospitals and ambulatory care settings. Our lead product candidate, injectable meloxicam, is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor that has successfully completed four Phase II clinical trials in the treatment of moderate to severe post-operative pain, and two pivotal Phase III clinical trials in patients following bunionectomy and abdominoplasty surgeries. As injectable meloxicam is not in the opioid class of drugs, we believe it 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.

In addition to developing proprietary drug candidates, we, through our subsidiary, Recro Gainesville LLC, or Recro Gainesville, leverage our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for Recro Gainesville as well as our research and development of proprietary product candidates.

Recent Developments

In November 2016, we announced positive results from the second of our two pivotal Phase III clinical trials for intravenous, or IV, meloxicam, evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty). In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in Summed Pain Intensity Difference, or SPID, over the first 24 hours, or SPID24, compared to placebo. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 219 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam (30mg bolus injection) or placebo in a 1:1 ratio, once every 24 hours. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID24 (p=0.0145) compared to the placebo arm. With the positive data from this study, we believe this completes the efficacy program for the IV meloxicam new drug application, or NDA.

Lead Product Candidate Injectable Meloxicam

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,

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and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990s 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 juvenile rheumatoid arthritis in patients 2 years or older. We believe that IV 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.

In early 2016, based on feedback from the U.S. Food and Drug Administration, or FDA, we commenced our Phase III clinical trial program for IV meloxicam. The program includes two pivotal Phase III clinical trials, both of which IV meloxicam has successfully completed. In July 2016, we announced positive results from one pivotal clinical trial, evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy). In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in SPID over the first 48 hours, or SPID48, compared to placebo. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 201 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam (30mg bolus injection over 15-30 seconds) or placebo in a 1:1 ratio, once every 24 hours for up to three doses following bunionectomy surgery, a representative hard tissue surgery. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID48 (p=0.0034) compared to the placebo arm. The study also achieved 15 of the 19 secondary endpoints, including statistically significant differences in SPID6 (p=0.0153), SPID12 (p=0.0053), SPID24 (p=0.0084), SPID24-48 (p=0.0050), time to first use of rescue medication (p=0.0076), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo. The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events, or SAEs, or bleeding events in the IV meloxicam-treated patients. The most common adverse events, or AEs, occurring in at least 3% of IV meloxicam-treated treated patients, were nausea, headache, pruritus, constipation vomiting, dizziness, flushing and somnolence, and were comparable to the placebo group. The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs, or TEAEs, were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

In November 2016, we announced positive results from the second of our two pivotal clinical trials, evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty). In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in SPID24, compared to placebo. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 219 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam (30mg bolus injection) or placebo in a 1:1 ratio, once every 24 hours. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID24 (p=0.0145) compared to the placebo arm. The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 (p=0.0434), time to perceptible pain relief (p=0.0050), subjects with ³30% improvement at 24 hours (p=0.0178), number of times patients required rescue in the first 24 hours after randomization (p=0.0275), as well as number of times rescued from 24 to 48 hours (p=0.0009), and several other pain relief metrics, compared to placebo. The safety results demonstrated that IV meloxicam was well tolerated with no difference in SAEs related to bleeding for IV meloxicam treated patients versus placebo (1 each). There were two additional SAEs observed in the placebo group. The most common (³2% in the IV meloxicam group) AEs were nausea, headache, vomiting, and dizziness. The incidence of these events was lower than those observed in the placebo group. The majority of AEs were mild in nature and one patient in the placebo group discontinued treatment due to an adverse event of post-procedural bleeding. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

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To complete our Phase III program, we are currently enrolling patients following a variety of surgical conditions in an additional safety study of IV meloxicam. The population selected for inclusion in the safety study is intended to replicate real world use of injectable meloxicam. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. If we continue to observe a favorable safety profile in our additional safety studies, we anticipate filing an NDA for IV meloxicam in the summer of 2017. We plan to pursue a Section 505(b)(2) regulatory strategy for IV meloxicam.

Recro Gainesville

Through our subsidiary, Recro Gainesville, we leverage our formulation and development expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. 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. In a typical collaboration, we license certain intellectual property to our commercial partners and work with our commercial partners to develop product candidates, or new formulations of existing product candidates. In these collaborations, we also typically exclusively manufacture and supply clinical and commercial supplies of these product candidates. These collaborations result in revenue streams including from royalties, profit sharing, research and development and manufacturing, which support continued operations for Recro Gainesville as well as our research and development of proprietary product candidates. We currently develop and/or manufacture the following products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®, as well as development stage products.

Our Pipeline Product Candidates

We also have a pipeline with other early-stage product candidates. Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, is in a class of drugs called alpha-2 adrenergic agonists and is an FDA approved and commercial injectable drug, sold by Hospira, Inc. in the United States under the brand name Precedex® and by Orion Corporation, or Orion, in Europe under the brand name Dexdor®. We previously studied Dex-IN for the treatment of post-operative pain, but based on clinical trial results and feedback from the FDA, we are exploring other potential indications for Dex-IN, including for the treatment of peri-procedural pain. We also have a sublingual formulation of Dex, Dex-SL, which may be appropriate for use in treating chronic pain. In addition to Dex-IN and Dex-SL, we have another selective alpha-2 agonist product candidate in our pipeline, Fadolmidine, or 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.

Intellectual Property

We own patents and patent applications for injectable meloxicam, that cover compositions, including compositions produced using NanoCrystal® technology, method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual, royalty-free basis, composition and methods of making patent and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030.

We own various controlled release formulation patents, including patents in the United States, Canada, and Europe, related to our proprietary delivery technologies that we utilize in our drug development, formulation and manufacturing business through Recro Gainesville. These patents are scheduled to expire between 2019 and 2026. We own patents and patent applications in the United States and Canada 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 extension.

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We also hold patent applications directed to the analgesia indication, formulations and intranasal and transmucosal methods of use of Dex, and we are progressing through the patent application process globally, including the United States. Several patent applications have issued as patents outside the United States for transmucosal methods, and the resulting patent protection in the United States will last into 2030, subject to extension.

Our Strategy

We intend to maximize the value of our product candidates. Our strategy to achieve this goal includes:

- Advance IV meloxicam through clinical development and regulatory approval for moderate to severe pain.
- Commercialize IV meloxicam in the United States independently or with third parties.
- Expand our development, formulation and manufacturing business.
- Enter into strategic partnerships to maximize the potential of our product candidates outside of the United States.
- Leverage our management and development experience to explore other indications for injectable meloxicam and to develop our other pipeline product candidates.
- Acquire additional products and product candidates.

Financial Information

We have a limited operating history. In addition to revenue generated from Recro Gainesville, we have funded our operations to date primarily from proceeds received from public offerings and 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 closed our IPO in which we sold 4,312,500 shares of common stock for net proceeds of approximately $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. On August 19, 2016, we closed an underwritten public offering in which we sold 1,986,666 shares of common stock at a price per share of $7.50 for net proceeds of approximately $13.4 million. As of November 30, 2016, we have sold 1,143,940 shares of common stock under a common stock purchase agreement with Aspire Capital, LLC, or the Aspire Agreement, for net proceeds of approximately $7.8 million.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in November 2007. Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2470.

Available Information

Our website address is *www.recropharma.com*. The information contained in, or accessible through, our website does not constitute part of this prospectus. We make available free of charge on our website our annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or the SEC. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website as part of this prospectus.

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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. These risks are discussed more fully in the Risk Factors section of this prospectus immediately following this prospectus summary and in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K filed with the SEC on March 24, 2016, which is incorporated by reference in this prospectus. These risks include the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We depend substantially on the successful completion of our Phase III clinical trial program for injectable meloxicam. The positive clinical results obtained for injectable meloxicam in earlier clinical studies may not be repeated in our remaining Phase III safety study and, thus, we may never receive regulatory approval of injectable meloxicam.
- We have only recently begun to generate revenue through our acquisition of our contract manufacturing facility, royalty and formulation business, but we may never be profitable.
- Revenues from our manufacturing business are dependent on a small number of commercial partners, and the loss of one of these partners, or a decline in their orders, may adversely affect our business. Our four largest customers generated 96% of our revenues for the nine months ended September 30, 2016, of which one customer generated 43% of our revenue under two separate customer agreements, and another customer generated 38% of our revenue.
- We depend substantially on the successful completion of clinical trials for our other product candidates. The positive results obtained for these other product candidates in earlier pre-clinical and clinical studies may not be repeated and, thus, we may never receive regulatory approval of these other product candidates.
- Even if we obtain FDA approval for injectable meloxicam or our other product candidates in the United States, we may never obtain approval for or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.
- We have incurred substantial indebtedness, which could adversely affect our business.
- We use third parties to assist with conducting, supervising and monitoring portions of our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- We are subject to intense competition and, if we are unable to compete effectively, our product candidates may not reach their commercial potential.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (1) the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2020, (2) the beginning of the first fiscal year after our annual gross revenue is $1.0 billion or more, (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging

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growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We will take advantage of these reporting exemptions until we are no longer an emerging growth company.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Summary Financial Data

We derived the consolidated statements of operations data presented below for the years ended December 31, 2015 and 2014 from our audited financial statements. The consolidated statements of operations data for the nine months ended September 30, 2016 and 2015, and the consolidated balance sheet data as of September 30, 2016, are derived from our unaudited interim financial statements. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year or any other period. The following information should be read in conjunction with our consolidated financial statements and related notes incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

The pro forma as adjusted balance sheet data as of September 30, 2016 reflects receipt of the estimated net proceeds of $36.9 million from the sale of 6,430,868 shares of our common stock in this offering at an assumed offering price of $6.22 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on December 12, 2016, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

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	Year ended December 31,		Nine months ended September 30,	
	2015	2014	2016	2015
	(in thousands, except share and per share data)			
Statements of Operations Data:				
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 49,284	$	$ 50,260	$ 32,824
Research and development revenue	2,668		1,713	2,375
Total revenue	51,952		51,973	35,199
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	28,054		25,563	19,228
Research and development	12,281	7,874	23,175	7,260
General and administrative	13,017	3,998	9,263	8,492
Amortization of intangible assets	1,884		1,937	1,238
Change in warrant valuation	(1,560)		47	119
Change in contingent consideration valuation	5,246		7,705	2,586
Total operating expenses	58,922	11,872	67,690	38,923
Operating loss	(6,970)	(11,872)	(15,717)	(3,724)
Other income (expense):				
Interest income	12	11	27	10
Interest expense	(5,560)	(4,273)	(4,279)	(3,888)
Net loss before income taxes	(12,518)	(16,134)	(19,969)	(7,602)
Income tax benefit	15,551		166	
Net income (loss)	3,033	(16,134)	(19,803)	(7,602)
Accretion of redeemable convertible preferred stock		(1,270)		
Net income (loss) applicable to common shareholders	3,033	(17,404)	(19,803)	(7,602)
Basic net income (loss) per common share	$ 0.36	$ (2.79)	$ (2.01)	$ (0.92)
Diluted net income (loss) per common share	$ 0.21	$ (2.79)	(2.01)	(0.92)
Weighted average basic common share outstanding	8,491,025	6,238,581	9,862,526	8,243,909
Weighted average diluted common share outstanding	8,749,234	6,238,581	9,862,526	8,243,909

	As of September 30, 2016		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 24,752	$ 28,373	65,253

Working capital	37,736	41,357	78,237
Total assets	146,009	149,630	186,510
Debt (including current portion)[3]	24,236	24,236	24,236
Total shareholders equity	40,631	44,252	81,132

(1) The pro forma column reflects the sale of 500,000 shares of common stock for approximately $3.6 million in net proceeds under the Aspire Agreement between October 1, 2016 and November 30, 2016.

(2) Pro Forma as adjusted to give effect to the pro forma adjustments set forth in footnote 1, and to further reflect the sale of 6,430,868 shares being offered in this offering, and the receipt of the estimated net proceeds of $36.9 million from the sale of these shares, at an assumed offering price of $6.22 per share, the last reported sales price for our common stock on the Nasdaq Capital Market on December 12, 2016, and after deducting the underwriting discounts and commissions and estimated offering

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expenses payable by us. Each $1.00 increase (decrease) in the assumed public offering price, would increase (decrease) the amount of cash and cash equivalents, working capital, total assets and total shareholders equity by approximately $6.0 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares of common stock to be issued by us in this offering. Each increase (decrease) of 1,000,000 shares offered by us would increase (decrease) the as adjusted amount of cash and cash equivalents, working capital, total assets and total shareholders equity by approximately $5.8 million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the underwriters at pricing.

(3) Includes principal balance outstanding of $27,347, net of unamortized deferred issuance costs of $3,111.

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The Offering

Common stock offered by us	6,430,868 shares (7,395,498 shares if the underwriters option to purchase additional shares is exercised in full).
Common stock to be outstanding after this offering	18,294,528 shares (19,259,158 shares if the underwriters option to purchase additional shares is exercised in full).
Option to purchase additional shares	The underwriters have the option to purchase from us up to a maximum of 964,630 additional shares of common stock. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $36.9 million. ($42.5 million if the underwriters option to purchase additional shares is exercised in full), assuming an offering price of $6.22 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on December 12, 2016. The actual offering price per share will be as determined between us and the underwriters at the time of pricing. We intend to use the net proceeds from this offering to fund the NDA filing and regulatory approval process and preparatory commercial activities for IV meloxicam, our planned IV meloxicam Phase IIIB program, and for general corporate purposes. See Use of Proceeds.

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Risk Factors	An investment in our common stock involves a high degree of risk. See Risk Factors beginning on page 11 of this prospectus and the similarly titled sections in the documents incorporated by reference into this prospectus .
NASDAQ Capital Market symbol	REPH

Outstanding Shares

The number of shares of our common stock to be outstanding after this offering is based on 11,863,660 shares of our common stock outstanding as of September 30, 2016, and assumes the issuance and sale of 6,430,868 shares of our common stock in this offering, and excludes:

- 2,343,819 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2016 at a weighted-average exercise price of $7.00 per share;
- 19,975 shares of our common stock issuable upon the vesting and settlement of restricted stock units outstanding as of September 30, 2016;
- 174 shares of our common stock available for future issuance as of September 30, 2016 under our 2008 Stock Option Plan;
- 855,022 shares of our common stock available for future issuance as of September 30, 2016 under our Amended and Restated Equity Incentive Plan;
- 784,928 shares of our common stock issuable upon the exercise of outstanding warrants as of September 30, 2016 with a weighted average exercise price of $12.05 per share; and
- 500,000 shares of our common stock sold from October 1, 2016 to November 30, 2016 under the Aspire Agreement.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, does not assume or give effect to the exercise of options or warrants outstanding as of September 30, 2016.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below and those discussed under the Section captioned Risk Factors contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which is incorporated by reference in this prospectus, together with the information included in this prospectus and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks Related to This Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion with respect to the use of proceeds of this offering, including for any of the purposes described in the section of this prospectus entitled Use of Proceeds. You will be relying on the judgment of our management regarding the application of the proceeds of this offering. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could harm our business, delay the development of our product candidates and cause the price of our common stock to decline.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the public offering price for our common stock in this offering is substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering, you will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. See the section titled Dilution below for a more detailed discussion of the dilution you will incur if you purchase shares in this offering.

Issuances of shares of common stock or securities convertible into or exercisable for shares of common stock following this offering, as well as the exercise of options and warrants outstanding, will dilute your ownership interests and may adversely affect the future market price of our common stock.

The issuance of additional shares of our common stock could be dilutive to shareholders if they do not invest in future offerings. We intend to use the net proceeds from this offering to fund the NDA filing and regulatory approval process and preparatory commercial activities for IV meloxicam, our planned IV meloxicam Phase IIIB program, and for general corporate purposes. We will need additional capital to fund the completion of our commercial infrastructure, including milestone payments, and post-launch activities for IV meloxicam, subject to final regulatory approval. We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements, which may cause your ownership interest to be diluted.

In addition, we have a significant number of options and warrants to purchase shares of our common stock outstanding. If these securities are exercised, you may incur further dilution. Moreover, to the extent that we issue additional options or warrants to purchase, or securities convertible into or exchangeable for, shares of our common stock in the future and those options, warrants or other securities are exercised, converted or exchanged, shareholders may experience further dilution.

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A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

Upon completion of this offering, based on our shares outstanding as of December 12, 2016, we will have 18,802,959 shares of common stock outstanding based on the issuance and sale of 6,430,868 shares of our common stock in this offering. Of these shares, only 3,205,759 are subject to a contractual lock-up with the underwriters for this offering for a period of 90 days following this offering. In addition, our stockholders SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., owners of an aggregate of 3,098,955 of the shares of common stock subject to the contractual lock-up, each have an exception to their respective lock-up permitting the sale of up to 40,000 shares of common stock pursuant to a rule 10b5-1 plan trading plan beginning after the 60th day of the contractual lock-up period. These shares can be sold, subject to any applicable volume limitations under federal securities laws, after the earlier of the expiration of, or release from, the 90-day lock-up period. The balance of our outstanding shares of common stock, including any shares purchased in this offering, may be resold into the public market immediately without restriction, unless owned or purchased by our affiliates. Moreover, some of the holders of our common stock have the right, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

As of November 30, 2016, there were approximately 2,407,681 shares subject to outstanding options and restricted stock unit awards or that are otherwise issuable under our equity compensation plans, all of which shares we have registered under the Securities Act of 1933, as amended, on a registration statement on Form S-8. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above, to the extent applicable.

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FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus or the documents incorporated herein 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, plan, predict, project, similar expressions are intended to identify forward-looking statements, although not 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 injectable meloxicam or our other product candidates, and any future clinical and preclinical studies;
- unfavorable new clinical data and additional analyses of existing clinical data;
- whether results of early clinical trials will be indicative of the results of future clinical trials and whether interim results from a clinical trial will be predictive of the final results of the clinical trial;
- 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; and

our ability to meet required debt payments, including any milestone payments owing to Alkermes plc, 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 and the documents that we incorporate by reference herein 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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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 6,430,868 shares of common stock in this offering will be $36.9 million, or $42.5 if the underwriters exercise their option to purchase additional shares in full, assuming an offering price of $6.22 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on December 12, 2016, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

We intend to use the net proceeds from this offering to fund the NDA filing and regulatory approval process and preparatory commercial activities for IV meloxicam, our planned IV meloxicam Phase IIIB program, and for general corporate purposes. We will need additional capital to fund the completion of our commercial infrastructure, including milestone payments, and post-launch activities for IV meloxicam, subject to regulatory approval.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including our ability to gain access to additional financing, the relative success and cost of our research, preclinical and clinical development programs and whether we are able to enter into future licensing or collaboration arrangements. As a result, our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering. Pending their ultimate use, we intend to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities.

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MARKET PRICE OF OUR COMMON STOCK

Our common stock has been listed on the Nasdaq Capital Market under the symbol REPH since our initial public offering on March 12, 2014. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices per share for our common stock on the Nasdaq Capital Market for the periods indicated:

	HIGH	LOW
2016		
First Quarter	$ 9.20	$ 5.59
Second Quarter	$ 8.62	$ 5.95
Third Quarter	$ 12.50	$ 7.51
Fourth Quarter (through December 12, 2016)	$ 10.17	$ 6.10
2015		
First Quarter	$ 9.93	$ 2.80
Second Quarter	$ 15.40	$ 6.56
Third Quarter	$ 18.30	$ 11.06
Fourth Quarter	$ 12.86	$ 7.58
2014		
First Quarter (beginning March 12, 2014)	$ 9.88	$ 7.00
Second Quarter	$ 8.49	$ 5.01
Third Quarter	$ 8.10	$ 2.71
Fourth Quarter	$ 3.39	$ 2.36

On December 12, 2016, the closing price of our common stock as reported by the Nasdaq Capital Market was $6.22 per share. As of December 12, 2016, there were approximately 9 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our credit facility with OrbiMed. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

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BUSINESS

Overview

We are a revenue-generating, specialty pharmaceutical company primarily focused on developing innovative products for hospitals and ambulatory care settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor, the oral form of which has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990s as Mobic®. IV meloxicam has successfully completed four Phase II clinical trials in the treatment of moderate to severe post-operative pain, and two pivotal Phase III clinical trials, one evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy) and the other evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty). We believe that IV 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. To complete our Phase III program, we are currently enrolling patients following a variety of surgical conditions in an additional safety study of IV meloxicam. The population selected for inclusion in the safety study is intended to replicate real world use of injectable meloxicam. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. If we continue to observe a favorable safety profile in our additional safety studies, we anticipate filing an NDA for IV meloxicam to the FDA in the summer of 2017. As a non-opioid product, we believe injectable meloxicam will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory depression and constipation while maintaining analgesic, or pain relieving, effects. We are pursuing a Section 505(b)(2) regulatory strategy for injectable meloxicam.

In addition to developing proprietary drug candidates, we, through our subsidiary Recro Gainesville, leverage our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for Recro Gainesville as well as our research and development of proprietary product candidates. Recro Gainesville operates a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia. We currently develop and/or manufacture the following products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®, as well as development stage products.

Our pipeline also includes other early-stage product candidates. Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, is in a class of drugs called alpha-2 adrenergic agonists, and 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®. We previously studied Dex-IN for the treatment of post-operative pain, but based on clinical trial results and feedback from the FDA, we are exploring other potential indications for Dex-IN, including for the treatment of peri-procedural pain. We also have a sublingual formulation of Dex, Dex-SL, which may be appropriate for use in treating chronic pain. In addition to Dex-IN and Dex-SL, we have another selective alpha-2 agonist product candidate in our pipeline, Fadolmidine, or Fado, which we believe also shows promise in neuropathic pain based on preclinical data.

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Pipeline

Corporate History and Significant Milestones

We were incorporated in 2007, and began operating in 2008.

In March 2014, we closed our IPO in which we sold 4,312,500 shares of common stock for net proceeds of approximately $30.3 million.

In February 2015, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire, under which, as of November 30, 2016, we have sold 1,143,940 shares of common stock for net proceeds of approximately $7.8 million.

In April 2015, we completed a transformative acquisition in which we acquired from Alkermes plc, or Alkermes, certain assets, including the worldwide rights to injectable meloxicam and our development, formulation and manufacturing business now operating through Recro Gainesville, which we refer to herein as the Gainesville Transaction. This 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 Recro Gainesville employees. The consideration paid consisted of $50.0 million, a $4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of our common stock at an exercise price of $19.46 per share. In addition, we may be required to pay up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and a percentage of future product net sales related to injectable meloxicam.

In April 2015, to fund the up-front payment due to Alkermes, we entered into a credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed. 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. As of September 30, 2016, we have paid down approximately $22.7 million, or 45%, of the original $50.0 million of the senior secured term loan from the business s excess cash flow generated.

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In July 2015, we completed 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.

In July 2016, we announced positive results from a Phase III pivotal clinical trial evaluating our lead product candidate, injectable meloxicam, in pain relief over a 48-hour period in a hard tissue, post-operative pain model.

In August 2016, we closed an underwritten public offering in which we sold 1,986,666 shares of common stock at a price per share of $7.50, for net proceeds of approximately $13.4 million after deducting underwriting commissions and offering expenses.

In November 2016, we announced positive results from the second of our Phase III pivotal clinical trial evaluating our lead product candidate, injectable meloxicam, in pain relief over a 24-hour period in a soft tissue, post-operative pain model.

Our Strategy

We intend to maximize the value of our product 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. Our broader corporate strategy includes the following:

Advance IV meloxicam through clinical development and regulatory approval for moderate to severe pain. Our key goal is to file an NDA, and receive FDA approval of IV meloxicam for the management of moderate to severe pain as soon as possible. IV meloxicam has recently successfully completed two pivotal Phase III clinical trials. To complete our Phase III program, we are currently enrolling patients following a variety of surgical conditions in an additional safety study of IV meloxicam. If we continue to observe a favorable safety profile in our additional safety studies, we anticipate filing the NDA for IV meloxicam with the FDA in the summer of 2017.

Commercialize IV meloxicam in the United States independently or with third parties. We believe IV meloxicam targets a narrow group of specialist prescribers which would allow for the successful marketing and commercialization by a company of our size. We are currently preparing for a potential U.S. commercial launch of IV meloxicam, if approved, and we plan to establish sales, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Expand our development, formulation and manufacturing business. We are focused on expanding our development, formulation and manufacturing services. We intend to seek additional manufacturing and development partnerships with commercial partners through ongoing business development efforts, as well as through expansion of our proprietary drug delivery technologies, and service offerings.

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.

Leverage our management and development experience to explore other indications for injectable meloxicam and to develop our other pipeline product candidates. If we have sufficient additional resources, we plan to evaluate injectable meloxicam for potential additional indications. In addition, our early-stage product pipeline includes proprietary drug solutions for peri-procedural pain and pain resulting from cancer, musculoskeletal disorders and peripheral neuropathy, utilizing multiple delivery systems, including intrathecal/epidural, transdermal, intranasal and sublingual platforms. Our goal is to

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leverage our drug development expertise along with innovative delivery systems to develop these product candidates to improve quality of life for the millions of people suffering from moderate-to-severe pain annually.

Acquire additional products and product candidates. We may identify and license, co-promote or acquire products or product candidates for development for use in hospital or ambulatory care settings.

Our Lead Product Candidate Injectable Meloxicam

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 1990s 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 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, or 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 IV or intramuscular, or IM, administration routes.

Post-Operative Pain Market

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 a January 2016 article in the New England Journal of Medicine, overdose deaths from prescription painkillers (defined to mean opioid or narcotic pain relievers) have increased significantly over the past 14 years. It notes the following trends:

- Prescription painkiller overdoses killed 18,893 people in the United States in 2014;
- In 2014, about 10.3 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year; and
- Emergency department visits involved with misusing or abusing prescription opioid painkillers increased 153% between 2004 and 2011.

We believe that injectable meloxicam offers an attractive alternative for relief of moderate to severe pain without the risks associated with opioids, and we believe that the majority of patients to be served would be in the post-operative setting. 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 post-operative pain relief without the adverse issues associated with opioids.

Injectable Meloxicam Advantages

We believe injectable meloxicam has a number of advantages over existing, FDA approved analgesics, including the following:

Not considered a controlled substance. Meloxicam is not an opioid and not 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.

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, which is defined by inadequate ventilation leading to increased carbon dioxide levels and respiratory acidosis, is an established outcome of opioid use. One of the more concerning adverse effects of chronic opioid use, for which tolerance does not develop, is respiratory depression during sleep, which 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 formulation results in a more rapid onset of pain relief of less than 10 minutes. Ketorolac, for example, can take up to 30 minutes for the onset of pain relief.

Duration of pain relief. IV meloxicam utilizing NanoCrystal™ technology has demonstrated the potential to be an effective analgesic for up to 18 to 24 hours after a single dose in clinical trials. IV forms of ketorolac, ibuprofen and acetaminophen provide effective pain relief up to four to six hours, resulting in the need for four to six doses for every 24 hours.

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

Administration. We believe that IV meloxicam has an administration advantage in terms of bolus injection, whereas ibuprofen and acetaminophen can take up to 15 to 30 minutes to infuse. In addition, there is an IM formulation of meloxicam, while neither ibuprofen nor acetaminophen currently have IM formulations.

Clinical Development

Multiple clinical trials have been conducted to evaluate the safety, pharmacokinetics and analgesic potential of IV meloxicam. Based on the results of these trials, we believe IV meloxicam has the potential to be a potent analgesic in the management of moderate to severe pain. In early 2016, based on feedback from the FDA, we commenced our Phase III clinical trial program for IV meloxicam. The program includes two pivotal Phase III clinical trials, both of which IV meloxicam has successfully completed. To complete our Phase III program, we are currently enrolling patients following a variety of surgical conditions in an additional safety study of IV meloxicam. The population selected for inclusion in the safety study is intended to replicate real world use of injectable meloxicam. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. If we continue to observe a favorable safety profile in our additional safety study, we anticipate filing an NDA for IV meloxicam in the summer of 2017.

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Phase III Clinical Trials

Study REC-15-016

In July 2016 we announced positive results from one pivotal clinical trial, evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy). In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in SPID over the first 48 hours, or SPID48, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following bunionectomy surgery. Two hundred and one patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg) or placebo once daily for three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 7 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 48-hour period of IV meloxicam when administered as a bolus injection (over 15-30 seconds).

The primary efficacy endpoint of the trial was SPID48, utilizing a windowed 2-hour last observation carried forward, or W2LOCF, analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, and patient global assessment, or PGA, of pain control. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID48 (p=0.0034) compared to the placebo arm (Figure 1).

Figure 1: SPID48

The study also achieved 15 secondary endpoints, including statistically significant differences in SPID6 (p=0.0153), SPID12 (p=0.0053), SPID24 (p=0.0084), SPID24-48 (p=0.0050), time to first use of rescue medication (p=0.0076), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo (Table 1).

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Table 1: Summary of Secondary Endpoints

Parameter		p-value
SPID6		0.0153
SPID12		0.0053
SPID24		0.0084
SPID24-48		0.0050
Time to First Rescue Analgesia		0.0076
Number of Subjects Rescued 0-24 Hours		0.0002
Number of Subjects Rescued 24-48 Hours		0.0009
Number of Subjects Rescued 0-48 Hours		0.0002
Number of Times Rescued 0-24 Hours		0.0025
Number of Times Rescued 24-48 Hours		0.0108
Number of Times Rescued 0-48 Hours		0.0014
% Subjects with >30% Improvement	6 Hours	0.0451
% Subjects with >30% Improvement	24 Hours	0.0107
% Subjects with >50% Improvement	24 Hours	0.0430
PGA of Pain Control at 48 hours		0.0046

Times to Perceptible and Meaningful Pain Relief, % Subjects with >50% Improvement within 6 Hours, PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that IV meloxicam was well tolerated with no SAEs or bleeding events in the IV meloxicam-treated patients. The most common AEs occurring in at least 3% of IV meloxicam-treated treated patients, were nausea, headache, pruritus, constipation vomiting, dizziness, flushing and somnolence, and were comparable to the placebo group (Table 2). The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs, or TEAEs, were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

Table 2: Adverse Events reported by ³3% of subjects from any treatment group

	n (%) of Subjects	
Preferred Term	N1539 30 mg (N=100)	Placebo (N=101)
Subjects with ³1 TEAE	44 (44.0)	54 (53.5)
Nausea	20 (20.0)	26 (25.7)
Headache	8 (8.0)	12 (11.9)
Vomiting	3 (3.0)	9 (8.9)
Pruritus	8 (8.0)	3 (3.0)
Decreased appetite	2 (2.0)	7 (6.9)
Constipation	4 (4.0)	5 (5.0)
Abdominal pain		6 (5.9)
Dizziness	3 (3.0)	4 (4.0)
Flushing	3 (3.0)	1 (1.0)
Somnolence	3 (3.0)	2 (2.0)
ALT increased		3 (3.0)

** Two (2) subjects experienced Serious Adverse Events during this study. Both subjects were randomized to placebo.

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Study REC-15-015

In November 2016, we announced positive results from the second of our two pivotal clinical trials, evaluating pain relief over a 24 hour period in a soft tissue, post-operative pain model (abdominoplasty). In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in SPID over the first 24 hours, SPID24, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following abdominoplasty surgery. Two hundred nineteen patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg) or placebo once daily for three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 7 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 24-hour period of IV meloxicam when administered as a bolus injection (over 15-30 seconds).

The primary efficacy endpoint of the trial was SPID24 (0-24), utilizing a W2LOCF analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, time to pain relief and PGA of pain control. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID24 (p=0.0145) compared to the placebo arm (Figure 2).

Figure 2: SPID24

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The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 (p=0.0434), time to perceptible pain relief (p=0.0050), subjects with ³30% improvement at 24 hours (p=0.0178), number of times patients required rescue in the first 24 hours after randomization (p=0.0275), as well as number of times rescued from 24 to 48 hours (p=0.0009), and several other pain relief metrics, compared to placebo (Table 3).

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Table 3: Summary of Secondary Endpoints

Parameter	p-value
SPID12	0.0434
SPID48	0.0040
SPID24-48	0.0028
Number of Subjects Rescued 24-48 Hours	0.0014
Number of Times Rescued 0-24 Hours	0.0275
Number of Times Rescued 24-48 Hours	0.0009
Number of Times Rescued 0-48 Hours	0.0027
Time to Perceptible Pain Relief	0.0050
% Subjects with ³30% Improvement 24 Hours	0.0178
PGA of Pain Control at 48 hours	0.0027

SPID6, Times to Meaningful Pain Relief and First Rescue, Number of Subjects rescued 0-24 and 0-48 hours, % Subjects with ³30 and ³50% Improvement within *6* Hours and ³50% within 24 hours, PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that IV meloxicam was well tolerated with no difference in SAEs related to bleeding for IV meloxicam treated patients versus placebo (1 each). There were two additional SAEs observed in the placebo group. The most common (³2% in the IV meloxicam group) AEs were nausea, headache, vomiting, and dizziness (Table 4). The incidence of these events was lower than those observed in the placebo group. The majority of AEs were mild in nature and one patient in the placebo group discontinued treatment due to an adverse event of post-procedural bleeding. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

Table 4: Adverse Events reported by ³2% of subjects from any treatment group

	n (%) of Subjects	
Preferred Term	N1539 30 mg (N=110)	Placebo (N=109)
Subjects with >=1 TEAE	58 (52.7)	80 (73.4)
Nausea	30 (27.3)	41 (37.6)
Headache	13 (11.8)	18 (16.5)
Vomiting	5 (4.5)	10 (9.2)
Dizziness	4 (3.6)	10 (9.2)

** Four (4) subjects experienced Serious Adverse Events during this study. Three subjects were randomized to placebo and one to N1539.

Phase II Clinical Trials

Study REC-15-014

This was a Phase II, randomized, single-center, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following bunionectomy surgery. Fifty-nine patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg or 60 mg dosage groups) or placebo once daily for two days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 7 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate the safety of IV meloxicam when administered as a bolus injection (over 15-30 seconds).

The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events, bleeding events or injection site reactions. The most common AEs were nausea, headache, dizziness,

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pruritus and vomiting and were comparable to the placebo group. There were no discontinuations due to AEs. The majority of TEAEs were mild in nature and determined by investigators to be not related or possibly related to study drug. There were no vital signs changes that necessitated treatment. There were no observed changes in the evaluation of ECGs. No clinically meaningful lab changes were observed in the meloxicam treatment groups (Table 5).

Table 5: Adverse Events reported by ³2% of subjects from any treatment group

		IV Meloxicam	
	Placebo	**30 mg**	**60 mg**
	N = 19	**N = 20**	**N = 20**
	n (%)	**n (%)**	**n (%)**
Nausea	4 (21.1)	6 (30.0)	4 (20.0)
Headache	4 (21.1)	2 (10.0)	3 (15.0)
Dizziness	1 (5.3)	3 (15.0)	2 (10.0)
Pruritus	0 (0.0)	1 (5.0)	2 (10.0)
Vomiting	1 (5.3)	3 (15.0)	0 (0.0)
Decreased appetite	2 (10.5)	0 (0.0)	1 (5.0)
Erythema	1 (5.3)	2 (10.0)	0 (0.0)
Constipation	0 (0.0)	1 (5.0)	1 (5.0)
GGT increased	2 (10.5)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	2 (10.0)	0 (0.0)
Somnolence	0 (0.0)	1 (5.0)	1 (5.0)

The primary efficacy endpoint of the trial was SPID48 (0-48), utilizing the last observation carried forward, or LOCF, analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, and patient global assessment, or PGA, of pain control. Both the 30 mg and 60 mg IV meloxicam treatment arms demonstrated statistically significant reductions in pain intensity, as measured by SPID48 (p=0.0007 and p=0.0027, respectively) compared to placebo (Figure 3). Although there were observed differences in opioid consumption among the meloxicam dose groups and the placebo group, in general these differences did not meet statistical significance.

Figure 3: SPID48

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Pain intensity was measured at various time points throughout the study. Differences in pain intensity were observed as early as 10 minutes and continued throughout the 48 hour observation period. Overall the 30 mg and 60 mg dose groups performed in a very comparable fashion (Figure 4).

Figure 4: Pain Intensity Differences for Each Time Point

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. Following surgery on post-operative day 1, or Post Op Day 1, subjects received a single dose of either IV placebo, morphine or meloxicam 5 mg, 7.5 mg, 15 mg, 30 mg or 60 mg. 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 pain intensity and pain relief were made using the 100-mm VAS to assess pain intensity and a 5-point categorical scale (ranging from none to complete) to assess pain relief.

Overall, all active treatment doses produced statistically significant reductions in SPID24 (a co-primary endpoint) compared to placebo ($p < 0.001$), utilizing the LOCF analysis method. In addition, all active treatment doses also produced statistically significant improvement in TOTPAR24 (a co-primary efficacy endpoint) compared to placebo ($p < 0.001$). Statistically significant decreases in pain intensity from baseline were detected as early as 10 minutes post-dose 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 5).

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Figure 5: 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 6. The median time to rescue (based on the lower bound of the 95% confidence interval for the 50th 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).

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Figure 6: Percentage of Subjects Using Rescue Medication

Study medication was well tolerated. A total of five 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 event rates were generally low and consistent with this surgical population under study (Table 6).

Table 6: Adverse Events reported by ³3% of subjects from any treatment group

			IV Meloxicam				
	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)

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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. 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. SPID24 was the primary endpoint utilizing the LOCF analysis method for this study.

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, as well as in every efficacy analysis.

The onset of action was rapid for the IV meloxicam doses, with statistically significant differences in pain intensity and pain reduction detected among the treatments as early as 10 minutes. For the IV meloxicam doses, analgesia was sustained, with statistically significant differences in pain intensity and pain relief evident through 24 hours postdose.

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 reported in this study. There were no clinically meaningful trends in vital signs or laboratory assessments. Adverse event rates were generally low and consistent with this surgical population.

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. 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 s discontinuation. Although a full efficacy analysis was not completed due to the early termination, analysis of the data from the enrolled subjects demonstrated that IV meloxicam 30 mg once daily produced a statistically significant difference compared to placebo for the 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. One 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.

Pharmacokinetic Studies

Pharmacokinetic studies have examined single and multiple doses of IV meloxicam. In general terms, IV 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.

Recro Gainesville

Through our subsidiary, Recro Gainesville, we leverage our formulation and development expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for

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commercial partners who commercialize or plan to commercialize these products. 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. In a typical collaboration, we license certain intellectual property to our commercial partners and work with our commercial partners to develop product candidates, or new formulations of existing product candidates. We also typically exclusively manufacture and supply clinical and commercial supplies of these product candidates. These collaborations result in revenue streams including from royalties, profit sharing, research and development and manufacturing, which support continued operations for Recro Gainesville as well as our research and development of proprietary product candidates.

The table below details the key products developed and/or manufactured with our commercial partners:

Product	Indication	Technology	Territory	Revenue Source	Commercial Partner
Ritalin LA®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Royalty	Novartis Pharma AG
Focalin XR®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide, except Canada	Manufacturing Royalty	Novartis Pharma AG
Verelan PM®	Hypertension	OCR (SODAS)	United States	Manufacturing Royalty	Lannett Company, Inc.
Verapamil (generic)	Hypertension	OCR (SODAS)	United States	Manufacturing Profit Sharing	Teva Pharmaceutical Industries Ltd.
Zohydro ER®	Severe Pain	OCR (SODAS)	United States	Manufacturing Royalty	Pernix Therapeutics, Inc.
			Canada	Manufacturing Royalty	Paladin Labs, Inc.

In addition to these key products, we also develop and manufacture other development stage products. The manufacture of these products for clinical trials and commercial use is subject to cGMPs and other regulatory agency regulations. We own and operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, which has been inspected by U.S., EU, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

With each product, we either purchase active drug product from third parties or receive it from our commercial partners to formulate product using our technologies. 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 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 also hold cGMP certifications for EU importation of products made in Gainvesville for sale in the EU.

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

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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, and manufacturing and related data to the relevant regulator or sponsor to provide adequate manufacturing support in respect of the product. We generally update this information annually with the relevant regulator.

Customer Agreements

We are party to agreements with each of our commercial partners governing the development, formulation and/or supply services were provide, as well as any applicable intellectual property licenses. Each commercial partner generally remains responsible for distributing, marketing and promoting their respective products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for Gainesville as well as our research and development of proprietary product candidates. We are dependent on a small number of commercial partners, with our four largest customers (Teva Pharmaceutical Industries, Inc., Novartis AG, Pernix Therapeutics, Inc. and Lannett Company, Inc.) having generated 96% of our revenues for the nine months ended September 30, 2016, of which one customer generated 43% of our revenue under two separate customer agreements, and another customer generated 38% of our revenue.

During the nine months ended September 30, 2016 and year ended December 31, 2015, revenue under one of our customer agreements, with Watson Laboratories, Inc., a subsidiary of Teva Pharmaceutical Industries Ltd., or Teva, represented 38% and 33% of our revenues, respectively. Pursuant to the amended and restated license and supply agreement, or the License and Supply Agreement, between us and Watson Laboratories, Inc., we exclusively manufacture generic Verapamil for Teva. We receive a percentage profit share from Teva 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). Under the License and Supply Agreement, we also license certain intellectual property to Teva and maintain the regulatory approval that is necessary to enable Teva to distribute Verapamil in the United States. Teva 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®. The License and Supply Agreement renews for one-year terms annually unless terminated by either party by providing notice in advance of the renewal date.

Our Pipeline Candidates

Dex

Dex is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Hospira currently markets IV Dex as a sedative trademarked Precedex® in the United States, and Orion markets IV Dex as an ICU sedative in the European Union, trademarked as Dexdor®. Dex has an extensive history of safe intravenous use. We have formulated Dex-IN, a proprietary intranasal formulation of Dex, at a significantly lower dose (perhaps as low as 1/10th) 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.

We initially studied Dex-IN for the treatment of post-operative pain. 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 determined not to pursue Dex-IN in post-operative pain due to time, cost and associated risk. We are exploring the possibility of evaluating Dex-IN 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.

We also have a sublingual formulation of Dex, Dex-SL, which may be appropriate for use in treating chronic pain.

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Fado

We also have another selective alpha-2 agonist product candidate in our pipeline, Fado. 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. In Orion sponsored studies, Fado appeared to delay the onset of pain while doses of Fado greater than 120 mcg also appeared to suppress pain. In addition, Fado was well tolerated by subjects.

Intellectual Property

Injectable Meloxicam

We own patents and patent applications for injectable meloxicam, that cover compositions, including compositions produced using NanoCrystal® technology, method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual, royalty-free basis, composition and methods of making patent and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030.

Recro Gainesville

We also own various controlled release formulation patents, including patents in the United States, Canada, and Europe, related to our proprietary delivery technologies that we utilize in our drug development, formulation and manufacturing business through Recro Gainesville. These patents are scheduled to expire between 2019 and 2026. We own patents and patent applications in the United States and Canada directed to the composition of, manufacturing of, and formulating of Zohydro ER®. We license our U.S. patents and patent applications to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States. We also own Canadian patents and patent applications relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. The patent protection for Zohydro ER® provides for protection of Zohydro ER® through 2034, subject to any extensions or disclaimers.

Our Pipeline Candidates

We hold patent applications directed to the analgesia indication, formulations and intranasal and transmucosal methods of use of Dex, and we are progressing through the patent application process globally, including the United States. Several patent applications have issued as patents outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. If the intranasal patent applications are issued as patents, the resulting patent protection will last into 2032, subject to any disclaimers or extensions. Also for Fado, we have a pro-drug patent that expires in 2025.

We are party to 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, worldwide, except for 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 have the right to sublicense the rights under such license at any time. We are required to pay Orion lump sum payments on the achievement of certain developmental milestones and upon the achievement of certain commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. We will pay milestone payments to Orion of up to 20.5 million ($23.0 million as of September 30, 2016) after regulatory

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approval of Dex dosage forms and upon achieving certain sales milestones. Through September 30, 2016, no such milestones have been achieved. The initial term of this license is 15 years from the first commercial sale in the Territory, with automatic two year extensions, unless either party provides written notice of termination.

We are also party to 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 ($13.7 million as of September 30, 2016), 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%. Through September 30, 2016, no such milestones have been achieved. The initial term of this license is 15 years from the first commercial sale in the Territory, with automatic three year extensions, unless either party provides written notice of termination at least six months prior to expiration or unless otherwise terminated pursuant to the terms of the license agreement.

Intellectual Property Protection Strategy

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.

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. We note that the patent laws of foreign countries differ from those in the United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

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.

We are currently preparing for a potential U.S. commercial launch of IV meloxicam, if approved, and we plan to establish sales, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Manufacturing and Supply of our Product Candidates

We currently rely on contract manufacturers to produce drug product for our clinical studies under cGMPs, with oversight by our internal managers. 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 additional costs.

Injectable Meloxicam

Pursuant to a Development, Manufacturing and Supply Agreement, or Supply Agreement, Alkermes (through a subsidiary), will provide (i) clinical and commercial bulk supplies of IV meloxicam formulation, and (ii) development services with respect to the Chemistry, Manufacturing and Controls section of the NDA for IV meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk IV meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV 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 meloxicam formulation exclusively from Alkermes. 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.

Dex and Fado

We are party to an API supply agreement with Orion, whereby Orion provides us with API for the development and commercialization of the Dex and Fado product candidates. 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. 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.

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, 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.

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 to obtain 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 injectable 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 injectable 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 currently market therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Endo Pharmaceuticals, Inc., Mallinckrodt plc 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. Additionally, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., Durect Corporation, Heron Therapeutics, Inc., Pacira, Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

With our development, formulation and manufacturing business, we compete with contract pharmaceutical formulation and manufacturing companies such as Catalent, Inc., Patheon Holdings

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Coöperatief U.A., Adare Pharmaceuticals, Inc., Metrics, Inc., a subsidiary of Mayne Pharma Group Limited, and other packaging and manufacture-related service providers.

Government Regulation

Governmental authorities in the United States at the federal, state and local level, and other in 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 injectable 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 enforcement or judicial sanctions. This enforcement could include, without limitation, the FDA s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or 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.

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, some of which must be conducted 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;