REXAHN PHARMACEUTICALS, INC.
Form DEFA14A
March 11, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

(Rule 14a−101)

Proxy Statement Pursuant to Section 14(a)
of the Securities Exchange Act of 1934

Filed by the Registrant
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Check the appropriate box:

Preliminary Proxy Statement
Confidential, For Use of the Commission Only (as permitted by Rule 14a−6(e)(2))
Definitive Proxy Statement
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Rexahn Pharmaceuticals, Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

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March 11, 2019

Dear Fellow Shareholders,

I am writing to provide you with an overview of Rexahn Pharmaceuticals' (referred to in this letter as we, us, Rexahn or the Company) current status and prospects, and to request your support on a proposal to be considered at a Special Meeting of Shareholders to be held on March 26, 2019, at 8:00 a.m. (local time), at the Radisson Hotel, 3 Research Court, Rockville, Maryland 20850.

Biotechnology is one of the most exciting and rewarding industries to be involved with when the drugs are promising, they demonstrate strong clinical results and receive favorable regulatory outcomes. It is our goal to bring novel and much needed treatments into the hands of physicians, bringing hope to patients and achieve financial success for our shareholders. However, research is not always successful. A 2016 study by the Biotechnology Industry Organization demonstrated that the likelihood of a drug eventually receiving U.S. Food and Drug Administration approval once it enters clinical trials was less than 10%. In oncology, the success rate was just over 5%. I don't share these statistics with you to excuse Rexahn's past performance, but rather, to put the timelines, risks, successes and failures into perspective. We operate in a high-risk field where success requires not only compelling science, but patience, investment, thoughtful risk mitigation, and often a bit of luck. And even with successes, the timelines to get to approval and market are long and the investment required at each stage of development is high.

Rexahn has clearly had some bumps in the road, and to realize the potential of our pipeline we need to refocus and invest where we see the greatest potential to improve patient outcomes and drive shareholder value. Since I assumed the chief executive role in November 2018, we have taken several steps to restructure our operations and position the Company for future growth. We decreased our operating costs, added significant talent to the board of directors (Board), and rightsized our clinical spending to focus on opportunities where we see the greatest opportunities for success.

In order to achieve our objectives, we believe it will be important to maintain our listing on NYSE American, or on another national exchange such as the Nasdaq Stock Market (Nasdaq); enhance our profile with potential investors and collaborators; and improve our access to capital. The proposed reverse stock split to be considered at the Special Meeting of Shareholders is necessary for us to address these important considerations.

Overview of Rexahn Programs

RX-3117: Oral Small Molecule Nucleoside Analogue

RX-3117 is the subject of ongoing Phase 2a clinical trials in metastatic pancreatic cancer and advanced bladder cancer.

In November 2017, we initiated a Phase 2a trial of RX-3117 in combination with ABRAXANE® (paclitaxel protein-bound particles for injectable suspension). The multicenter, single-arm, open-label study is designed to evaluate the safety and efficacy of RX-3117 in combination with ABRAXANE in first-line metastatic pancreatic cancer patients. The primary endpoint in this trial is progression free survival. In February 2019, we reached the target enrollment of 40 evaluable patients in this trial. In January 2019, we presented updated preliminary safety and efficacy data at the 2019 American Society of Clinical Oncology Gastrointestinal Cancers (ASCO GI) Symposium. As of January 9, 2019, 36 patients were enrolled into the study, and 24 patients had at least one scan on treatment and were included in the evaluation of overall response. One patient (1/24, 4.2%) had a complete response after six cycles of treatment and eight patients (8/24, 33.3%) had a partial response. A further 13 patients had stable disease (13/24, 54.2%). The overall response rate was 38%, and the disease stabilization rate at eight weeks was 92%. The combination of RX-3117 and ABRAXANE appears to be safe and well-tolerated. The most commonly reported related adverse events were nausea, diarrhea, fatigue, alopecia, decreased appetite, rash, vomiting and anemia.

We are on track to complete this study as planned in the second half of this year. Since many patients are still being treated in the trial, it is too early to estimate progression free survival; however, we expect to report additional safety and efficacy data later this year.

Amongst the potential outcomes in this study is that the data will be sufficiently strong to advance directly to a pivotal trial, which would be a head-to-head comparison of RX-3117 in combination with ABRAXANE versus the combination of gemcitabine and ABRAXANE (one of the current standards of care treatments for first-line metastatic pancreatic cancer). Depending on the number of patients enrolled, such a study would likely take two to three years and at least $20 million to complete. It is our hope that data from our current study will be sufficiently robust and encouraging to warrant proceeding directly to a pivotal trial to support the regulatory approval of RX-3117 in metastatic pancreatic cancer. Alternatively, an additional Phase 2 study might be required before proceeding into a pivotal trial. As with any clinical trial, it is also possible that the data from the ongoing study may ultimately not be sufficient to continue RX-3117 development in pancreatic cancer.

We will know a lot more about the future of RX-3117 in metastatic pancreatic cancer later this year when progression free survival data becomes available from the ongoing Phase 2a trial. Access to capital facilitated by the proposed reverse stock split will enable us to take this program forward if warranted by the data.

In December 2018, we completed enrollment in the Phase 2a trial of RX-3117 in advanced bladder cancer. In February 2019, we presented updated data from this trial at the ASCO Genitourinary Cancers Symposium. Preliminary signs of efficacy, including a complete response, were observed. Of the 31 patients who had at least one scan on treatment and were therefore included in the preliminary efficacy analysis, five patients had stable disease for at least four months, two of whom stayed in the trial for six months or longer. Mild to moderate fatigue, nausea and diarrhea are the most common side effects observed in the trial to date.

We will continue to follow these patients and will provide an update when available. However, no additional trials are currently planned in advanced bladder cancer. Our focus of the RX-3117 program remains on metastatic pancreatic cancer.

RX-5902: Potential first-in-class orally administered modulator of the - catenin pathway

We initiated a Phase 2a clinical trial of RX-5902 in patients with metastatic triple negative breast cancer (TNBC) in February 2017 and ceased enrollment of this trial in December 2018. This purpose of this trial was to evaluate safety and preliminary signs of efficacy of RX-5902 in patients who have failed multiple prior treatments. As of October 12, 2018, 17 patients had been enrolled in the trial, with 13 of these patients evaluable and six showing a clinical response, including one patient who had an 18% reduction in tumor size and two patients experiencing progression free survival greater than 200 days. Data generated to date do not support further development of RX-5902 as a monotherapy for TNBC.

We are encouraged by the preclinical data showing the ability of RX-5902 to potentiate checkpoint therapy in an animal model of human TNBC. In August 2018, we entered into a collaboration with Merck to evaluate the combination of RX-5902 and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase 2 trial in patients with metastatic TNBC. We are currently evaluating the development strategy for RX-5902 and may or may not proceed with this trial.

Business Development Strategy:

We seek to identify, develop and bring to market novel products to improve patient outcomes in cancers that are difficult to treat. We may improve our chances of success by forging collaborative relationships and investments with partners for commercialization, development and co-investment. Business development activities are a crucial aspect of our strategy. We continue to evaluate the development paths for RX-3117 and RX-5902 and have an active business development effort that seeks partners for our programs at key value inflection points to maximize shareholder value.

Last year, we entered into a research and development collaboration with Zhejiang Haichang Biotechnology Co., Ltd. (Haichang) for the development of RX-0301. Under the agreement Haichang will develop RX-0301, a nano-liposomal formulation of RX-0201 (Archexin®), using its proprietary QTsome™ technology and conduct certain pre-clinical and clinical activities through completion of a Phase 2 proof-of-concept clinical trial for the treatment of hepatocellular carcinoma (HCC). Haichang is funding development activities through completion of the Phase 2a clinical trial up to an aggregate amount of $10,000,000. Rexahn and Haichang will share, in an agreed ratio, the downstream licensing fees and royalties paid by third parties in connection with the further development and commercialization of RX-0301 for the treatment of HCC.

Rexahn recently formed a business development committee to assist the Board with its oversight of Rexahn's business development activities with the goal of maximizing the value of the Company's current and future development programs.

Potential paths to value creation:

A key value determinant for Rexahn will be additional data in the Phase 2a combination clinical trial with ABRAXANE in newly diagnosed pancreatic cancer patients, which is expected later this year. We are also working towards additional business development transactions that have the possibility of bringing non-dilutive capital to Rexahn and expanding the opportunities for our existing and future product candidates.

Proposal to authorize a reverse stock split of our issued and outstanding common stock:

We are requesting authorization to proceed with a reverse stock split in order to, among other things, enhance our profile to investors and potential collaborators. We believe that the reduction in the number of issued and outstanding shares of our common stock (Common Stock) caused by the reverse stock split, together with the anticipated increased stock price immediately following and resulting from the reverse stock split, may provide the following benefits:

Increase Our Common Stock Price to a Level More Appealing for Investors.

We believe that the reverse stock split could enhance the appeal of our Common Stock to the financial community, including institutional investors, the investing public, and brokerage firms, who may be reluctant to invest in or recommend lower-priced securities to their clients. This is due in part to a perception that lower-priced securities are less promising as investments, are less liquid, or are less likely to be followed by institutional securities research firms and therefore more likely to have less third-party analysis of the Company available to investors.

Enhance Our Profile for Potential Collaborators

A key component of our corporate strategy is to seek to establish strategic alliances and partnerships with larger biotechnology and pharmaceutical companies to support the development and commercialization of our drug candidates. We believe that a number of potential collaborators are reluctant to partner with companies that lack reasonable access to capital and trade at very low share prices. Because the reverse stock split will have the effect of increasing our authorized but unissued shares of Common Stock, our access to capital will be enhanced, further facilitating our business development strategy.

Maintaining our Listing on the NYSE American

Our Common Stock is listed on the NYSE American. We may be delisted from the NYSE American if our stock is trading for a substantial period of time at a low price per share and we fail to effect a reverse stock split within a reasonable time after being notified that the NYSE American deems such action to be appropriate under all the circumstances. While we have not received such a notice from the NYSE American, increasing the price of our Common Stock would provide us with a greater opportunity to avoid the receipt of such a communication in the future.

Delisting from the NYSE American may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of the Common Stock. Delisting also could have other negative impacts, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. Moreover, we are committed in connection with the sale of securities to use commercially reasonable efforts to maintain the listing of the Common Stock during such time that certain warrants are outstanding.

Listing on Another National Securities Exchange

If the reverse stock split is approved, our Board will consider whether it is in the best interests of our shareholders to seek a listing of our Common Stock on the Nasdaq Stock Market or potentially another national securities exchange. Potential benefits of listing on Nasdaq or another national securities exchange include improved visibility of our Common Stock, enhanced trading liquidity and greater exposure to institutional investors. Eligibility for listing on Nasdaq is subject to a number of criteria, such as minimum share price, number of shareholders, market capitalization, and other factors, and there can be no assurance that we would satisfy the applicable listing requirements. Application for or approval of our Common Stock for listing on Nasdaq or another national securities exchange is not a condition or requirement for effecting the reverse stock split.

The Rexahn Board encourages shareholders to vote in favor of the reverse stock split proposal. Rexahn is at a very critical point in the evaluation of our pipeline. With shareholder approval, we believe we will be able to advance RX-3117 in response to positive data or, if necessary, reposition Rexahn towards potential new opportunities. Both leading independent proxy advisory firms Institutional Shareholder Services Inc. and Glass Lewis also recommend that our shareholders vote for this proposal.

Concluding Remarks:

I understand that Rexahn Common Stock has not historically performed well, and that losses have been significant for many of you. It may be challenging for some investors to support proposals recommended by the Rexahn Board. I completely understand your disappointment and frustration. However, a strong rationale exists to effect a reverse stock split of our issued and outstanding Common Stock, which will enable us to implement strategies to maximize Rexahn's potential value. I appreciate that you are taking the time to read this letter to learn more about our prospects and our reasons for convening the Special Meeting of Shareholders. If you would like to vote, or otherwise have questions about voting, you can reach Alliance Advisors, LLC, who is assisting the Board with the solicitation of proxies, at 855-643-7453.

Despite our challenges, we believe that we have the right team in place to maximize our opportunities. Your collective voices have been heard and we have made recent changes to the management team and strengthened our Board to better position Rexahn for growth.

On behalf of our Board and the employees at Rexahn, I want to thank you for your continued interest and support of our Company. We look forward to keeping you updated on our progress as we move through 2019. We thank you for joining us on this important journey as we endeavor to improve the lives of cancer patients.

Sincerely,

Douglas J. Swirsky
President & CEO

Where to Find Additional Information

The Company filed a definitive proxy statement with the U.S. Securities and Exchange Commission (the "SEC") on February 14, 2019 in connection with the Special Meeting (such proxy statement and any supplements or amendments thereto, the "Special Meeting Proxy Materials"). The Special Meeting Proxy Materials contain important information about the Special Meeting. Shareholders are urged to read the Special Meeting Proxy Materials carefully. Shareholders are able to obtain free copies of the Special Meeting Proxy Materials and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov and at http://investors.rexahn.com/financial-information/sec-filings.

Participants in the Solicitation

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the proposal to approve an amendment to our Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our Common Stock at a ratio within the range of 1:5 to 1:15, as determined by the Board and with such reverse stock split to be effected at such time and date, if at all, as determined by the Board in its sole discretion. Information about the Company's directors and executive officers, including a description of their interests, by security holdings or otherwise, is available in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the Special Meeting Proxy Materials.

Cautionary Note Regarding Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the federal securities laws, including the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the Company’s plans, objectives, expectations and intentions with respect to cash flow requirements, future operations and products, enrollments in clinical trials, the path of clinical trials and development activities, and other statements identified by words such as “will,” “potential,” “could,” “can,” “believe,” “intends,” “continue,” “plans,” “expects,” “anticipate “may,” and other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause the Company’s actual results to be materially different than those expressed in or implied by the Company’s forward-looking statements. For the Company, particular uncertainties and risks include, among others, understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer; drug candidates being in early stages of development, including clinical development; the ability to successfully and timely complete clinical trials for our drug candidates in clinical development; reliance on third-party contract research organizations and other investigators and collaborators for certain research and development services; and the ability to form strategic alliances and partnerships with pharmaceutical companies and other partners with respect to certain of our product candidates. More detailed information on these and additional factors that could affect the Company’s actual results are described in the Company’s filings with the SEC, including the Company’s Annual Report on Form 10-K for the year ended December 31, 2018. All forward-looking statements in this communication speak only as of the date hereof. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.