REXAHN PHARMACEUTICALS, INC.
Form DEFA14A
August 07, 2018

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
Filed by a Party other than the Registrant
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
Definitive Additional Materials
Soliciting Material Pursuant to Section 240.14a−12

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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(1) Amount Previously Paid:
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(4) Date Filed:

August 7, 2018

Dear Rexahn Shareholders,

The mission of Rexahn Pharmaceuticals is to improve the lives of cancer patients by discovering and developing novel, highly targeted cancer therapies that are designed to maximize anti-cancer activity while minimizing the side effects and toxicity experienced with current cancer treatments.

Rexahn has made significant progress towards achieving these goals. In Phase 1 and 2 clinical trials, both RX-3117 and RX-5902 have been shown to be safe and well tolerated in cancer patients and preliminary evidence of clinical activity has been seen in metastatic pancreatic cancer, advanced bladder cancer and triple negative breast cancer patients. During 2018/2019, we are advancing our Phase 2 clinical development programs to include newly diagnosed cancer patients and will be combining RX-3117 and RX-5902 with existing anticancer agents as the Company believes that this approach may produce the maximal anti-cancer benefit to patients while maintaining a good overall safety profile.

We are providing you with this mid-year update on Rexahn's clinical development programs and upcoming key value inflection points for 2018 and 2019. I also want you to be aware of the rationale for the proposed increase in our authorized shares, so that you can make an informed decision on the proposal to be considered at the Special Meeting of Shareholders on August 30, 2018. This proposal is asking for approval of an increase in authorized shares from 50 million to 75 million shares.

Of the 50 million shares of common stock currently authorized, approximately 42.5 million shares have already been used for previous financings and for the Shareholder approved equity compensation plan. This leaves only 7.5 million shares of common stock available to execute our strategy of progressing our ongoing Phase 2a clinical trials to key value inflection points and completing strategic corporate partnerships.

Currently, the Company has sufficient cash to fund its existing clinical development programs for at least the next 12 months. However, the RX-3117/Abraxane combination trial in newly diagnosed pancreatic cancer patients is not scheduled to be completed until December 2019. This budget does not take into account initiating an RX-5902/immunotherapy trial in TNBC patients in January 2019, which would increase the cash burn rate. The rationale for this trial is described below. In order to adequately fund the Company to completion of the RX-3117/Abraxane trial and the RX-5902/immunotherapy trial (key value drivers, we believe, for completing major strategic partnerships) the Company will require access to additional capital. Based on anticipated capital needs, we do not believe that currently available authorized shares are sufficient to fund the Company to these value inflection points. In addition, the lack of sufficient authorized shares/capital may negatively impact the ability of the Company to complete a strategic collaboration because the inability to raise capital to continue our operations would limit our options and negatively affect our negotiating power with potential partners.

Therefore, we are seeking shareholder approval to increase the number of authorized shares of common stock and we ask for your support in approving this proposal.

Program Highlights:

RX-3117:
The current focus of the RX-3117 clinical development program is on metastatic pancreatic cancer and advanced bladder cancer. RX-3117 has been shown to be safe and well tolerated in cancer patients and preliminary evidence of efficacy has been seen in Phase 2 clinical trials, as described below.

Metastatic pancreatic cancer:

At the 2018 American Society of Clinical Oncology Gastrointestinal Cancers (ASCO GI) meeting (https://tinyurl.com/y8yjzjhy), Dr. Vincent Chung, MD, FACP, (Associate Clinical Professor at City of Hope Comprehensive Cancer Center) presented clinical data from a Phase 2a RX-3117 monotherapy clinical trial in end-stage metastatic pancreatic cancer patients, a majority of whom failed two or more prior cancer therapies (these patients have a mean survival of 1.5 months):

- 31% of RX-3117 treated patients had disease stabilization for two months or more (ranged from 2 months to 7.5 months)
  - Compares favorably to published data in second line patients where gemcitabine alone produced disease stabilization of two months or more in 17% of the patients
- One patient had a partial response (32.7% reduction in total tumor volume)

This safety and initial efficacy data allowed Rexahn to initiate a Phase 2a clinical trial of RX-3117 in newly diagnosed metastatic pancreatic cancer patients in combination with Abraxane®. We believe newly diagnosed metastatic pancreatic cancer patients represent the largest target market segment for RX-3117 estimated to be greater than $3 Billion per year.

We recently announced the completion of stage 1 of this combination study, which demonstrated that RX-3117 and Abraxane can be administered together at the maximal labeled dose of Abraxane and the full Phase 2 dose of RX-3117 without producing an increase in severe adverse events, which we believe may lead to better clinical outcomes. This differs from current standard of care (gemcitabine/Abraxane) where the doses of both gemcitabine and Abraxane (when given in combination) must be reduced from the maximum labeled doses to avoid life threatening toxicities (which may also reduce the potential benefit to patients due to under dosing of both drugs). We expect that this data will be presented at a major medical conference later this year. In stage 2, an additional 25 patients will be enrolled. Enrollment in stage 2 is expected to be completed in early 2019 with a final data readout expected in fourth quarter of 2019. These results will dictate the future development plan for RX-3117, which based on the data, may include a pathway to an accelerated regulatory approval.

Advanced bladder cancer:
At the American Society of Clinical Oncology (ASCO) 2018 annual meeting (https://tinyurl.com/y768acgo), Dr. Jacob J. Adashek, MD (City of Hope Comprehensive Cancer Center), presented preliminary clinical data from an ongoing Phase 2a clinical trial of RX-3117 in advanced bladder cancer in which patients had failed three or more prior cancer therapies (including gemcitabine and/or immunotherapy) and have an expected progression free survival (PFS) of 2 months:

- 25% of the patients had PFS of greater than 4 months (range 4.5 months to 10.5 months)
- One patient had a complete response (CR) (100% reduction in tumor burden)
- Four additional patients had tumor reductions of greater than 15%

The study is still ongoing with the current patients still being monitored and additional patients being enrolled. Any decision on the next step for this program will be made once this study is completed in early 2019.

RX-5902:
The current focus of the RX-5902 clinical development program is on metastatic triple negative breast cancer (mTNBC). There is nothing currently approved to treat women with mTNBC. To date, RX-5902 has been shown to be safe and well-tolerated in cancer patients and preliminary evidence of efficacy has been seen in a Phase 2a clinical trial.

Metastatic triple negative breast cancer (mTNBC):
At the American Society of Clinical Oncology (ASCO) 2018 annual meeting (https://tinyurl.com/y73xawvo), Dr. Jennifer Diamond, MD (University of Colorado Anschutz Cancer Center) presented initial clinical data from a Phase 2a clinical trial in mTNBC patients. Patients in this trial had previously received up to nine prior cancer therapies yet their disease is actively progressing. Of the first twelve patients treated:

- Two patients had progression free survival (PFS) of greater than 230 days
- An additional three patients had PFS of greater than 50 days
- One patient had a 18% reduction in tumor burden

The fact that treatment with RX-5902 alone was able to extend PFS and reduce tumor burden in some patients is very encouraging. The study is still ongoing with the current patients still being monitored and additional patients being enrolled. An update on the clinical data from this trial will be presented at a major medical conference later this year.

Preclinical data presented last year at the 2017 San Antonio Breast Cancer Symposium (https://tinyurl.com/y886tpkj) demonstrated that RX-5902 potentiated the ability of the immunotherapy drug nivolumab (Opdivo®) to kill mTNBC tumors by increasing immunogenicity of the tumor (making cancer cells more susceptible to being killed by immunotherapy).

In published Phase 2 clinical studies in mTNBC patients, the immunotherapy drugs Opdivo® or Keytruda® when administered alone were only effective in 9-16% of mTNBC patients. Due to the synergistic effects observed between RX-5902 and immunotherapy, Rexahn is currently evaluating the possibility of conducting a Phase 2a clinical study in mTNBC patients combining RX-5902 with an immunotherapy drug. Rexahn believes that the greatest clinical benefit in mTNBC may be achieved by combining RX-5902 with an immunotherapy drug. Rexahn anticipates finalizing the trial design during the second half of 2018 and dosing the first patient early in 2019. Initiating this clinical trial will increase our use of cash in 2019 and require raising additional capital to fund the trial to completion.

Business Development:
We continue to evaluate the development paths for RX-3117 and RX-5902 and we have an active business development effort that seeks partners for our programs at key value inflection points to maximize Shareholder value.

Earlier this year, we entered into a collaboration with Haichang Biotechnology Co., Ltd. for the development of RX-0201 for hepatocellular carcinoma. Although we were encouraged by the clinical data generated in metastatic renal cell carcinoma, this collaboration allows the program to pivot to a more commercially attractive indication and the initial development costs will be incurred by Haichang. This collaboration will also allow Rexahn to focus its own resources on advancing RX-3117 and RX-5902 through Phase 2 clinical development.

2018/2019 Key Value Inflection Points:
We believe the upcoming events listed below have the potential for further validating our programs and enhancing value for shareholders. These potential milestones include:

- RX-3117: Presentation of stage 1 clinical data from Phase 2a combination clinical trial with Abraxane in newly diagnosed pancreatic cancer patients (Q4 2018)
- RX-3117: Completion of Phase 2a combination clinical trial with Abraxane in newly diagnosed pancreatic cancer patients (Q4 2019)
- RX-3117: Completion of Phase 2a monotherapy trial in advanced bladder cancer (Q1 2019)
- RX-5902: Completion of Phase 2a monotherapy trial in mTNBC (March 2019)
- RX-5902: Initiation of a Phase 2a combination trial with an immunotherapy drug in mTNBC (Q1 2019)
- RX-5902: Complete enrollment in a Phase 2a combination trial with immunotherapy drug in mTNBC (Q3 2020)

Proposal for an increase in authorized shares:

As of August 6, 2018, Rexahn had $15.7 million (unaudited) of cash and investments on-hand , which will expect is sufficient to fund the company's currently expected cash flow requirements for its activities for at least the next 12 months. However, the RX-3117/Abraxane combination trial in newly diagnosed pancreatic cancer patients is not scheduled to be completed until December 2019. It is also important to note that our current cashflow guidance does not take into account initiating a RX-5902/immunotherapy trial in mTNBC patients in January 2019, which would increase our cash utilization. In order to adequately fund the company to completion of both the RX-3117/Abraxane trial and the RX-5902/immunotherapy trial (the key value drivers for completing major strategic partnerships) the Company will require access to additional capital, which we have historically raised through the sale of stock, which requires the availability of sufficient authorized shares of common stock that the company currently does not have. We have evaluated the use of debt financing to decrease our need for equity capital and do not believe that significant or sufficient borrowing capacity exists at this time.

As of July 23, 2018, Rexahn has 50 million authorized shares of common stock of which approximately 42.5 million shares have already been used for previous financings where common stock and warrants were issued and for the Shareholder approved equity compensation plan. This leaves only 7.5 million shares of common stock available to raise additional capital to fund our ongoing Phase 2a clinical trials to completion and/or complete a strategic partnering transaction which may involve a partner making an equity investment in the Company. In either case, Rexahn does not have sufficient authorized shares to accomplish these goals, and therefore is seeking shareholder approval to increase the number of authorized shares of common stock. Increasing the number of authorized shares does not mean that Rexahn will immediately issue these shares. The share increase will, however, provide flexibility to raise additional capital when needed to fund Rexahn's ongoing clinical development programs to key value inflection points.

At the Company's Annual Meeting of Shareholders in June 2018, the Board of Directors requested a 100% increase in authorized shares of Common Stock (from 50 million to 100 million shares). While this proposal received the support of the majority of shares voted at the meeting, it did not pass since it required a majority of the total outstanding shares of the company to vote in favor of the proposal.

Based on the level of support for the prior proposal and discussions with shareholders, the Board of Directors is convening the Special Meeting of shareholders to approve a smaller increase in authorized shares (from 50 million to 75 million shares). Based on our current circumstances, the increase in authorized shares is essential to adequately fund our ongoing Phase 2a clinical trials towards key value-inflection points and, we think, to complete a strategic partnership.

If this increase is not approved, shareholder value may be significantly harmed. The Company's ability to raise capital would be limited, and the resulting lack of funding could delay or suspend our ongoing clinical programs. In addition, it may be difficult to attract, retain and motivate the skilled and experienced employees required to conduct the ongoing clinical trials. Potential collaborations and partnerships would also be negatively impacted as the inability to access capital would limit our options and negatively affect our negotiating power with potential partners.

The Rexahn Board of Directors encourages shareholders to vote in favor of the proposal. Rexahn is at a very exciting point in its clinical development programs. With shareholder approval, we will be able to advance these programs with the goal of improving the lives of cancer patients which will in turn create significant shareholder value. Leading independent proxy advisory firm Institutional Shareholder Services Inc. ("ISS") also recommends that our shareholders vote for this proposal, stating that the size of the proposed increase is reasonable and that ISS has no concerns with our past use of shares. ISS advises mutual funds and similar organizations on how to vote on matters presented for approval at shareholder meetings.

Finally, I would like to address any confusion that may exist regarding the relationship of the proposed increase in authorized shares being requests now and last year's reverse stock-split. In May 2017, we effected a 1-for-10 reverse stock split which reduced the number of both outstanding common shares from 237 million to 23.7 million shares and the number of authorized shares from 500 million to 50 million shares. By reducing authorized shares by the same ratio as outstanding shares, we did not utilize the reverse split as an opportunity to increase our share issuing capacity. Instead, we presented the issue of an increase in authorized capital separately at the 2018 Annual Meeting in June 2018. At this meeting, this proposal did not pass. We are now presenting a revised proposal to you at the Special Meeting scheduled for August 30, 2018, to increase our authorized capital by a smaller percentage.

On behalf of our Board of Directors 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 2018 and 2019. We thank you for joining us on this important journey as we endeavor to improve the lives of cancer patients.

Sincerely,
Peter D. Suzdak, Ph.D.
CEO

Where to Find Additional Information

The Company filed a definitive proxy statement with the U.S. Securities and Exchange Commission (the "SEC") on July 23, 2018 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 the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of the Company's common stock. 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, 2017, its annual proxy statement filed with the SEC on April 23, 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, 2017 and its subsequent quarterly reports on Form 10-Q. 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.