# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 30, 2017

# **RIGEL PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 0-29889 (Commission File No.) 94-3248524 (IRS Employer Identification No.)

1180 Veterans Boulevard South San Francisco, CA, 94080 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (650) 624-1100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition

On January 30, 2017, Rigel Pharmaceuticals, Inc. (the "Company" or "Rigel") filed a preliminary prospectus supplement pursuant to Rule 424(b)(5) in which it disclosed that, although it has not finalized its financial statements for the year ended December 31, 2016, it expects to report that it had approximately \$74.8 million of cash, cash equivalents and short-term investments as of December 31, 2016. This amount is preliminary, has not been audited and is subject to change upon the completion of the audit of the Company's financial statements as of and for the year ended December 31, 2016. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2016.

## Forward-Looking Statements

This Item 2.02 of this report contains forward-looking statements, including, without limitation, statements relating to Rigel's cash position as of December 31, 2016. These forward-looking statements are based upon Rigel's current expectations. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation, risks related to changes in estimated cash position based on the completion of the Company's financial statement closing procedures and the audit of Rigel's financial statements, and other risks detailed in Rigel's filings with the U.S. Securities and Exchange Commission (the "SEC"). You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Rigel does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

The information in Item 2.02 of this report shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein shall not be incorporated by reference into any filing with the SEC made by Rigel, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 8.01 Other Events.

The Company is supplementing and updating certain aspects of the description of its business from that described under the heading, "Item 1. Business" in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 8, 2016. The updated Company disclosure is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

## Item 9.01. Financial Statements and Exhibits.

## (d) Exhibits.

(u) LAI	ints.
Exhibit	Description
99.1	Updated Company Disclosure.
	2
	SIGNATURE
Pursua duly autho	ant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto rized.
	RIGEL PHARMACEUTICALS, INC.
Dated: Jan	uary 30, 2017 By: <u>/s/ Dolly A. Vance</u> Dolly A. Vance Executive Vice President, General Counsel and Corporate Secretary
	3
	EXHIBIT INDEX
Exhibit	Description
<i>у)</i> .1	Opdated Company Disclosure.
	4

Unless otherwise indicated or the context requires otherwise, references in this Exhibit 99.1 to "Rigel," "the company," "we," "us" and "our" refer to Rigel Pharmaceuticals, Inc. The name Rigel Pharmaceuticals and our logo are our trademarks. All other trademarks, trade names or service marks included in this Exhibit 99.1 are the property of their respective owners.

### FORWARD-LOOKING STATEMENTS

This Exhibit 99.1 contains forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievement to be materially different from any future results, levels of activity, performance or achievements include, but are not limited to, statements about:

· our business and scientific strategies;

- the progress of our and our collaborators' product development programs, including clinical testing, and the timing of results thereof;
- our corporate collaborations and revenues that may be received from our collaborations and the timing of those potential payments;
- · our expectations with respect to regulatory submissions and approvals, including the filing of any NDAs or INDs;
- · existing and future regulations that affect our business;
- · our drug discovery technologies;
- · our research and development expenses;
- · protection of our intellectual property;
- · sufficiency of our cash resources and the length of time before which we will require additional funding; and
- · our operations and legal risks.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions intended to identify forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. We discuss many of these risks, uncertainties and other factors in greater detail under the sections captioned "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forwardlooking statements.

You should read carefully this Exhibit 99.1 completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

#### **Company Overview**

We are a clinical-stage biotechnology company dedicated to the discovery and development of novel, targeted drugs in the therapeutic areas of immunology, oncology and immuno-oncology. Our pioneering research focuses on signaling pathways that are critical to disease mechanisms. Our current clinical programs include clinical trials of fostamatinib, an oral spleen tyrosine kinase, or SYK, inhibitor, in a number of indications. We completed and reported results from the first Phase 3 clinical trial for immune thrombocytopenic purpura, or ITP, in August and in October 2016, we reported the results for a second Phase 3 study in ITP as well as the results for the Phase 3 open label extension study in ITP with fostamatinib. We are also conducting a Phase 2 clinical trial for fostamatinib in autoimmune hemolytic anemia, or AIHA, and a Phase 2 clinical trial for IgA nephropathy, or IgAN. In addition, we have two oncology product candidates in Phase 1 development with partners BerGenBio AS, or BerGenBio, and Daiichi Sankyo, or Daiichi.

#### **Clinical Stage Programs**

## Fostamatinib — Immune Thrombocytopenic Purpura

*Disease Background.* Chronic ITP affects an estimated 60,000 to 125,000 people in the U.S. In patients with ITP, the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. ITP patients can suffer extraordinary bruising, bleeding and fatigue as a result of low platelet counts. Current therapies for ITP include steroids, blood platelet production boosters that imitate thrombopoietin, or TPOs, and splenectomy.

*Orally-Available SYK Inhibitor Program.* Taken in tablet form, fostamatinib blocks the activation of SYK inside immune cells. ITP is typically characterized by the body producing antibodies that attach to healthy platelets in the blood stream. Immune cells recognize these antibodies and affix to them, which activates the SYK enzyme inside the immune cell, and triggers the destruction of the antibody and the attached platelet. When SYK is inhibited by fostamatinib, it interrupts this immune cell function and allows the platelets to escape destruction. The results of our Phase 2 clinical trial, in which fostamatinib was orally administered to sixteen adults with chronic ITP, published in Blood, showed that fostamatinib significantly increased the platelet counts of certain ITP patients, including those who had failed other currently available agents.

In October 2013, we met with the U.S. Food and Drug Administration, or the FDA, for an end-of-Phase 2 meeting for fostamatinib in ITP. Based on that meeting, we designed a Phase 3 clinical program, called fostamatinib in thrombocytopenia, or FIT, in which a total of 150 ITP patients were randomized into two identical multi-center, doubleblind, placebo-controlled clinical trials. The patients will have been diagnosed with persistent or chronic ITP, and have blood platelet counts consistently below 30,000 per microliter of blood. Two-thirds of the subjects will receive fostamatinib orally at 100 mg bid (twice daily) and the other third will receive placebo on the same schedule. Subjects were expected to remain on treatment for 24 weeks. At week four of treatment, subjects who failed to meet certain platelet count and met certain tolerability thresholds could have their dosage of fostamatinib (or corresponding placebo) increased to 150 mg bid. The primary efficacy endpoint of this program is a stable platelet response by week 24 with platelet counts at or above 50,000 per microliter of blood for at least four of the final six qualifying blood draws. In August 2015, the FDA granted our request for Orphan Drug designation to fostamatinib, our oral SYK inhibitor, for the treatment of ITP. On April 1, 2016, we announced that we completed enrollment for both studies in the FIT Phase 3 clinical program of fostamatinib in ITP. On August 30, 2016, we announced the results of the first study, reporting that fostamatinib met its primary efficacy endpoint. The study showed that 18% of patients receiving fostamatinib achieved a stable platelet response compared to none receiving a placebo control (p=0.0261). On October 20, 2016, we announced the results of the second study, reporting that the fostamatinib response rate was 18%, consistent with the first study. However, one patient in the placebo group (4%) achieved a stable platelet response, therefore the difference between those on treatment and those on placebo did not reach statistical significance (p=0.152) and the study did not meet its primary endpoint. In the combined dataset of both stable and transient responders for both Phase 3 studies, the fostamatinib response rate was 29%, compared to 2% for placebo, and patients who met the primary endpoint had their platelet counts of greater than 50,000/uL on more than 4 of the 6 visits between weeks 14 and 24. In the post-study analysis performed by Rigel, a transient response was defined to include patients achieving at least two consecutive median platelet counts over 50,000/uL during the trial without rescue, but who did not otherwise meet the stable response criteria. These patients benefited substantially and typically did so within weeks of initiating treatment, providing early feedback as to whether fostamatinib group versus the placebo group in the following subgroups: prior splenectomy or not; prior exposure to TPO agents or not; platelet counts below or above 15,000/uL of blood at baseline, demonstrating that t

Patients from the first two Phase 3 studies were given the option to enroll in a long-term open-label extension study and receive treatment with fostamatinib, also a Phase 3 trial. As of September 2016, 124 patients had been enrolled in this study. All the patients who responded to fostamatinib in the parent studies and enrolled in the long-term open-label extension study had a median platelet count of 106,500/uL of blood in this study. These patients have been exposed to fostamatinib for a median of 16 months through the combined parent and the long-term open-label extension study.

In addition, there were 44 placebo patients from the first two Phase 3 studies that enrolled in the long-term open-label extension study. 41 of these patients had at least 12 weeks of follow-up. Of those, 9 patients (22%) have achieved a prospectively defined stable platelet response, which is statistically significant (p=0.0078) and similar to the response rate fostamatinib achieved in the parent studies.

The most frequent adverse events were gastrointestinal-related, and the safety profile of the product was consistent with prior clinical experience, with no new or unusual safety issues uncovered. Data from both Phase 3 studies as well as our ongoing open-label extension study demonstrates the consistent benefit of fostamatinib in ITP. We plan to file a New Drug Application, or NDA, for fostamatinib in ITP in the first quarter of 2017 and would expect to receive a decision on approval from the FDA in the first quarter of 2018, with a potential commercial launch in the U.S. in the first half of 2018.

### Fostamatinib — IgAN

*Disease Background.* IgAN is an autoimmune disease that severely affects the functioning of the kidneys. An estimated 12,000 Americans are diagnosed with this type of glomerulonephritis each year, with 25% of its victims eventually requiring dialysis and/or kidney transplantation over time. IgAN is characterized by the deposition of IgA immune complexes in the glomeruli of the kidneys leading to an inflammatory response and subsequent tissue damage that ultimately disrupts the normal filtering function of the kidneys. By inhibiting SYK in kidney cells, fostamatinib may block the signaling of IgA immune complex receptors and arrest or slow destruction of the glomeruli.

*Orally-Available SYK Inhibitor Program.* Our Phase 2 clinical trial in patients with IgAN, called SIGN (SYK Inhibition for Glomerulonephritis) completed enrollment for the first cohort and is currently enrolling patients for the second cohort. In January 2017, we announced that the first cohort in the Phase 2 study of fostamatinib in IgAN was completed in various centers throughout Asia, the U.S. and Europe. This cohort evaluated the efficacy, safety, and tolerability of a low dose of fostamatinib (100mg BID, n=26; placebo n=12) as measured by change in proteinuria, renal function, and histology (comparing the pre- and post-study renal biopsies). The primary efficacy endpoint was the mean change in proteinuria from baseline at 24 weeks. The study found that at 24 weeks fostamatinib was well tolerated with a good safety profile. The initial data suggest a trend towards a greater reduction in proteinuria in fostamatinib treated patients relative to placebo. We are performing further analysis of data from the first cohort, particularly the histology review of the renal biopsies, as well as other secondary efficacy endpoints, which we will present later in 2017. The Phase 2 study for the second cohort, evaluating a higher dose of fostamatinib (150 mg) for IgAN, will finish enrollment in 2017, with full results in 2018.

#### Fostamatinib — AIHA

*Disease Background.* AIHA is a rare, serious blood disorder where the immune system produces antibodies that result in the destruction of the body's own red blood cells. Symptoms can include fatigue, shortness of breath, rapid heartbeat, jaundice or enlarged spleen. While no medical treatments are currently approved for AIHA, physicians generally treat acute and chronic cases of the disorder with corticosteroids, other immuno-suppressants, or splenectomy.

Research has shown that inhibiting SYK with fostamatinib may reduce the destruction of red blood cells. This disorder affects an estimated 40,000 Americans, for whom no approved treatment options currently exist.

*Orally Available SYK Inhibitor Program.* We initiated a Phase 2 clinical trial in patients with AIHA in February 2016. The trial is an open-label, multi-center, two-stage study that will evaluate the efficacy and safety of fostamatinib in patients with warm antibody AIHA who have previously received treatment for the disorder, but have relapsed. Stage 1 will enroll 17 patients who will receive 150 mg of fostamatinib orally twice a day for a period of 12 weeks. The patients will return to the clinic every two weeks for blood draws and medical assessment. The primary efficacy endpoint of this study is to achieve increased hemoglobin levels by week 12 of greater than 10 g/dL, and greater than or equal to 2 g/dL higher than baseline. Stage 2 will include an additional 20 patients who will receive the same treatment protocol as Stage 1. We expect to have results of the Stage 1 segment of the trial in 2017. With this data, we will evaluate the best way forward and potentially an expedited path for pursuing AIHA.

## **Research/Preclinical Programs**

We are conducting proprietary research in the broad disease areas of inflammation/immunology, immuno-oncology, cancers and muscle wasting/muscle endurance. Within each disease area, our researchers are investigating mechanisms of action as well as screening compounds against potential novel targets and optimizing those leads that appear to have the greatest potential.

We are conducting preclinical studies to identify a lead molecule for our IRAK program. Inhibitors of IRAK activity represent valuable therapeutic tools to treat cytokinedriven autoimmune and inflammatory diseases. We plan on selecting a molecule from our IRAK program for preclinical development in 2017. It is expected that the program will include clinical evaluation in immunology areas, such as for lupus, gout and/or psoriasis.

### Sponsored Research and License Agreements

We conduct research and development programs independently and in connection with our corporate collaborators. We do not have ongoing participation obligations under our agreements with BMS for the discovery, development and commercialization of cancer immunotherapies based on our small molecule TGF beta receptor kinase inhibitors, Aclaris Therapeutics International Limited for the development and commercialization of certain JAK inhibitors for the treatment of alopecia areata and other dermatological conditions, AsraZeneca for the development and commercialization of R256, an inhaled JAK inhibitor, BerGenBio for the development and commercialization of an oncology program, and Daiichi to pursue research related to a specific target from a novel class of drug targets called ligases.

Under these agreements, which we entered into in the ordinary course of business, we received or may be entitled to receive upfront cash payments, progress dependent contingent payments on events achieved by such partners and royalties on any net sales of products sold by such partners under the agreements.