RIGEL PHARMACEUTICALS INC Form 8-K October 29, 2018

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): October 26, 2018

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

(Address of principal executive offices)

94080

(Zip Code)

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

Not Applicable

(Former name or former address, if changed since last report)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company O

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. O

ITEM 1.01. ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

On October 26, 2018, Rigel Pharmaceuticals, Inc. (Rigel) entered into a collaboration and license agreement (the License Agreement) and a supply agreement (the Supply Agreement) with Kissei Pharmaceutical Co., Ltd. (Kissei) to develop and commercialize fostamatinib, each effective October 29, 2018. Pursuant to the terms of the License Agreement, Kissei received exclusive rights to commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan, and the Republic of Korea (Korea). The parties collaboration is governed through a joint governance committee and appropriate subcommittees.

Kissei is responsible for performing and funding all development activities for fostamatinib in Japan, China, Taiwan, and Korea; provided, however, that Rigel retains the co-exclusive right to conduct development activities in such countries. Rigel retained the global rights, excluding these Asian countries, to commercialize fostamatinib in all current and potential indications.

Under the terms of the License Agreement, Rigel receives an upfront cash payment of \$33 million, with the potential for an additional \$147 million in development and commercial milestone payments, and will receive mid to upper twenty percent, tiered, escalated net sales-based payments for the supply of fostamatinib.

Rigel remains responsible for the manufacture and supply of fostamatinib for all development and commercialization activities under the License Agreement. In connection with the License Agreement, Rigel also entered into the Supply Agreement with Kissei to supply bulk drug product to Kissei for use under the License Agreement.

Unless terminated earlier, the License Agreement has a term that continues, on a product-by-product and country-by-country basis, until the latter of (i) the expiration of certain patent claims related to fostamatinib, and (ii) ten years after the first commercial sale of fostamatinib; provided that the term may continue if Kissei elects to continue commercializing fostamatinib in Japan, China, Korea, or Taiwan and obtain its supply of fostamatinib for such purpose from Rigel. In such event, Rigel would continue to supply fostamatinib to Kissei at our cost to supply plus a markup. The License Agreement may be terminated for cause by either party based on uncurred material breach of the other party, bankruptcy of the other party, or for safety reasons. Rigel may terminate the License Agreement if Kissei challenges or opposes any patent covered by the License Agreement. Kissei may terminate the License Agreement without cause. Upon early termination by either party, all licenses granted by Rigel to Kissei will automatically terminate, and, except in the event of a termination by Kissei for Rigel s material breach, the licenses granted by Kissei to Rigel shall survive such termination and shall automatically become worldwide. Following termination by Rigel for cause, Kissei is prohibited from competing with Rigel for a period of time.

The foregoing descriptions of the License Agreement and Supply Agreement are not intended to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which will be filed with the Securities and Exchange Commission as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2018.

This Current Report on Form 8-K contains forward-looking statements relating to, among other things, the payments that will be received by Rigel under the Collaboration and License Agreement. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as planned, will, may, and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Rigel's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the commercialization of fostamatinib; risks that the FDA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that fostamatinib clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that fostamatinib may

have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel s product candidates; market competition; Rigel s partners ability to obtain marketing approval for fostamatinib; and whether and when any of the milestone payments or product transfer price payments will ever be paid under Rigel s collaboration agreements, as well as other risks detailed from time to time in Rigel s reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the period ended June 30, 2018. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

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SIGNATURES

Pursuant 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 duly authorized.

Dated: October 29, 2018 RIGEL PHARMACEUTICALS, INC.

By: /s/ Dolly A. Vance
Dolly A. Vance
Executive Vice President, General Counsel and Corporate
Secretary

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