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 22, 2019**

RIGEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-29889	**94-3248524**
(Commission File No.)	(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 ☐

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. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On January 22, 2019, Rigel Pharmaceuticals, Inc. ("Rigel") and Grifols Worldwide Operations Limited ("Grifols") entered into an exclusive commercialization license agreement (the "Commercialization Agreement") to commercialize fostamatinib disodium hexahydrate for the treatment, palliation, or prevention of human diseases, including chronic or persistent immune thrombocytopenia ("ITP"), autoimmune hemolytic anemia ("AIHA"), and IgA nephropathy in Europe and Turkey. The parties' efforts will be governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration's operation and strategic direction.

The Commercialization Agreement includes customary representations and warranties on behalf of Rigel as are customarily found in transactions of this nature, including representations and operative provisions as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The Commercialization Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

In consideration for the exclusive license and other rights contained in the Commercialization Agreement, Grifols will pay Rigel an upfront payment of $30.0 million. Rigel will be eligible to receive regulatory and commercial milestones of up to $297.5 million, which includes a $17.5 million payment for EMA approval of fostamatinib for the first indication, currently anticipated to be for the treatment of chronic ITP and a $2.5 million creditable advance royalty payment due upon EMA approval of fostamatinib in the first indication. Rigel will also receive tiered royalty payments ranging from the mid-teens to 30% of net sales of fostamatinib in Europe and Turkey. In return, Grifols will receive exclusive rights to fostamatinib for the treatment, palliation, or prevention of human diseases, including chronic or persistent ITP, AIHA, and IgA nephropathy, in Europe and Turkey. Grifols shall also receive an exclusive option to expand the territory to include the Middle East, North Africa and Russia (including Commonwealth of Independent States). Rigel retains the remaining global rights to fostamatinib outside the Grifols territories and those rights previously granted to Kissei Pharmaceuticals (in Japan, China, Taiwan and the Republic of Korea). Grifols will use diligent efforts to commercialize fostamatinib in countries where regulatory approval has been obtained.

Rigel will be responsible, and bear all associated costs and expenses, to (i) continue the extension portion of the phase 3 clinical trial for ITP currently on-going until marketing authorization application ("MAA") approval or until such clinical trial is concluded, and, to the extent agreed by the parties, conduct any other clinical trials of fostamatinib for ITP required by the EMA to obtain MAA approval until MAA approval is obtained from the EMA and (ii) conduct the planned phase 3 clinical trial for AIHA, and, to the extend agreed by the parties, any other follow up clinical trials of the Product for AIHA required by the EMA to obtain MAA. Grifols will be responsible for all territory-specific development activities that are for the benefit of Europe and Turkey. As part of the collaboration, the parties will enter into a supply agreement pursuant to which Rigel will manufacture, by itself or through a third party contract manufacturer, and supply fostamatinib to Grifols on an exclusive basis.

The Commercialization Agreement may be terminated for cause by either party based on regulatory reasons, uncured material breach by the other party, bankruptcy of the other party or for safety reasons. Rigel may terminate the agreement if Grifols challenges or opposes any patent covered by the Commercialization Agreement. After the first MAA approval of fostamatinib in Europe and Turkey, Grifols may terminate the Commercialization Agreement upon eighteen months' prior written notice following the second anniversary of the first MAA approval of fostamatinib in Europe and Turkey. Grifols will also have the right to terminate the Commercialization Agreement for Rigel's material breach of the supply agreement. If, by the second anniversary of the effective date of the Commercialization Agreement, the EMA has not approved the MAA for fostamatinib for ITP, Grifols will have the right to terminate the Commercialization Agreement in its entirety within six (6) months after such second anniversary by providing Rigel with at least sixty (60) days' written notice, and in such event only, Rigel is required to refund to Grifols $25.0 million of the upfront payment. Upon termination by either party, all licenses granted by Rigel to Grifols will automatically terminate. In the case Rigel is in acquisition discussions with a competing company selling plasma products and Grifols has not provided its consent to an assignment or transfer of the Commercialization Agreement to such company in the event such an acquisition were to occur, in accordance with a certain process, then the Commercialization Agreement terminates if such an acquisition occurs, and Rigel or the acquiring party shall pay Grifols a one-time payment of $60.0 million.

The description of the Agreement in this Current Report on Form 8-K does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be included as an exhibit to Rigel' Quarterly Report on Form 10-Q for the fiscal period ending March 31, 2019, to be filed with the Securities and Exchange Commission.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements relating to, among other things, Rigel's partnership with Grifols; Rigel's partnership with Kissei; Rigel's ability to achieve regulatory and commercial milestone payments under its agreement with Grifols; Rigel's interactions with the EMA; and the timing of the EMA's MAA review process and when Rigel expects a decision. Any statements contained in this Current Report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "planned," "will," "may," "expect," "anticipate," 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 and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; 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 September 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.

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: January 23, 2019

RIGEL PHARMACEUTICALS, INC.

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