

**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): February 23, 2020

Kadmon Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37841
(Commission
File Number)

27-3576929
(I.R.S. Employer
Identification No.)

450 East 29th Street
New York, NY
(Address of principal executive offices)

10016
(Zip Code)

Registrant's telephone number, including area code (833) 900-5366

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	KDMN	The New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01**Other Events.**

On February 23, 2020, Kadmon Holdings, Inc. (the “Company”) issued a press release announcing expanded results from the previously reported interim analysis of ROCKstar (KD025-213), its ongoing pivotal trial of KD025 in chronic graft-versus-host disease. The data were presented today in the oral late-breaker session at the 2020 Transplantation & Cellular Therapy Meetings. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report.

Item 9.01**Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.**Description**

99.1

[Press release, dated February 23, 2020, issued by Kadmon Holdings, Inc.](#)

SIGNATURE

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.

Date: February 24, 2020

Kadmon Holdings, Inc.

/s/ Harlan W. Waksal

Harlan W. Waksal

President and Chief Executive Officer



Kadmon Announces Expanded Results of Interim Analysis of Pivotal Trial of KD025 in cGVHD

Patient Analyses and Safety Data Continue to Underscore Positive Impact of KD025 in cGVHD

Pre-NDA Meeting with FDA Planned for March 2020; Topline Results of Primary Analysis to be Announced in Q2 2020

NEW YORK, February 23, 2020 – Kadmon Holdings, Inc. (NYSE: KDMN) today announced expanded results from the previously reported interim analysis of ROCKstar (KD025-213), its ongoing pivotal trial of KD025 in chronic graft-versus-host disease (cGVHD). The data were presented today in the oral latebreaker session at the 2020 Transplantation & Cellular Therapy (TCT) Meetings.

As announced in November 2019, KD025 met the primary endpoint of Overall Response Rate (ORR) at the study's planned interim analysis, two months after completion of enrollment. KD025 showed statistically significant and clinically meaningful ORRs of 64% with KD025 200 mg once daily (95% Confidence Interval (CI): 51%, 75%; $p < 0.0001$) and 67% with KD025 200 mg twice daily (95% CI: 54%, 78%; $p < 0.0001$). In the expanded KD025-213 dataset presented today, ORRs were consistent with the previously reported interim analysis across key subgroups, including in patients with four or more organs affected by cGVHD (n=69; 64%), patients who had prior treatment with ibrutinib (n=45; 62%) and patients who had prior treatment with ruxolitinib (n=37; 62%). Three patients achieved a Complete Response. Responses were observed in all affected organ systems, including in organs with fibrotic disease. KD025 has been well tolerated: adverse events were consistent overall with those expected to be observed in cGVHD patients receiving corticosteroids, and no apparent increased risk of infection was observed. Additional secondary endpoints, including duration of response, corticosteroid dose reductions, Failure-Free Survival, Overall Survival and Lee Symptom Scale reductions continue to mature and will be available later in 2020.

"KD025 has been well tolerated and has already demonstrated high response rates in patients with severe and complex cGVHD after a median of five months of follow-up," said Corey Cutler, MD, MPH, FRCPC, Associate Professor of Medicine, Harvard Medical School; Medical Director, Adult Stem Cell Transplantation Program, Dana-Farber Cancer Institute and a KD025-213 study investigator and Steering Committee member.

"We are extremely pleased with the interim outcomes of this pivotal trial of KD025 in cGVHD, which track closely our findings from our earlier Phase 2 study. KD025 achieved robust response rates across all subgroups of this difficult-to-treat patient population, who had a median of four prior lines of therapy, and 73% of whom had no response to their last line of treatment," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We plan to meet with the FDA for a pre-NDA meeting in March 2020 and to announce topline results from the primary analysis of this trial in Q2 2020."

At the TCT Meetings, Kadmon also presented long-term follow-up data from KD025-208, its ongoing Phase 2 study of KD025 in cGVHD (Abstract #15205). These data were recently presented at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in December 2019.

About the ROCKstar (KD025-213) Trial

KD025-213 is an ongoing open-label trial of KD025 in adults and adolescents with cGVHD who have received at least two prior lines of systemic therapy. Patients were randomized to receive KD025 200 mg once daily or KD025 200 mg twice daily, enrolling 66 patients per arm. Statistical significance is achieved if the lower bound of the 95% CI of ORR exceeds 30%.

While the ORR endpoint was met at the interim analysis, which was conducted as scheduled two months after completion of enrollment, topline data from the primary analysis of the KD025-213 study, six months after completion of enrollment, will be reported in Q2 2020. Full data from the primary analysis will be submitted for presentation at an upcoming scientific meeting.

About KD025

KD025 is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates immune response as well as fibrotic pathways. In addition to cGVHD, KD025 is being studied in an ongoing Phase 2 clinical trial in adults with diffuse cutaneous systemic sclerosis (KD025-209). KD025 was granted Breakthrough Therapy Designation and Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of patients with cGVHD who have received at least two prior lines of systemic therapy.

About cGVHD

cGVHD is a common and often fatal complication following hematopoietic stem cell transplantation. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus and gastrointestinal tract. Approximately 14,000 patients in the United States are currently living with cGVHD, and approximately 5,000 new patients are diagnosed with cGVHD per year.

About Kadmon

Kadmon is a clinical-stage biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. Our clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies.

Forward Looking Statements

This press release contains forward-looking statements. Such statements may be preceded by the words “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, (i) the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; (ii) our ability to advance product candidates into, and successfully complete, clinical trials; (iii) our reliance on the success of our product candidates; (iv) the timing or likelihood of regulatory filings and approvals; (v) our ability to expand our sales and marketing capabilities; (vi) the commercialization of our product candidates, if approved; (vii) the pricing and reimbursement of our product candidates, if approved; (viii) the implementation of our business model, strategic plans for our business, product candidates and technology; (ix) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (x) our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; (xi) costs associated with defending

intellectual property infringement, product liability and other claims; (xii) regulatory developments in the United States, Europe, China, Japan and other jurisdictions; (xiii) estimates of our expenses, future revenues, capital requirements and our needs for additional financing; (xiv) the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; (xv) our ability to maintain and establish collaborations or obtain additional grant funding; (xvi) the rate and degree of market acceptance of our product candidates; (xvii) developments relating to our competitors and our industry, including competing therapies; (xviii) our ability to effectively manage our anticipated growth; (xix) our ability to attract and retain qualified employees and key personnel (xx) the potential benefits from any of our product candidates being granted orphan drug or breakthrough designation; (xxi) the future trading price of the shares of our common stock and impact of securities analysts' reports on these prices; and/or (xxii) other risks and uncertainties. More detailed information about Kadmon and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and subsequent Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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