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): July 19, 2021

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

Delaware	**001-37841**	**27-3576929**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

450 East 29th Street
New York, NY **10016**
(Address of principal executive offices) **(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:

☐ 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	Nasdaq Global Select Market

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 x

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. x

ITEM 8.01 Other Events

On July 16, 2021, Kadmon Holdings, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved REZUROCK™ (belumosudil) 200 mg once daily (QD) for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy.

The full text of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release issued by Kadmon Holdings, Inc., dated July 16, 2021.
104	Cover Page Interactive Data (embedded within Inline XBRL document)

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.

Kadmon Holdings, Inc.

Date: July 19, 2021

/s/ Harlan W. Waksal
Harlan W. Waksal, M.D.
President and Chief Executive Officer

U.S. FDA Grants Full Approval of REZUROCK™ (belumosudil) for the Treatment of Patients with Chronic Graft-Versus-Host Disease (cGVHD)

– REZUROCK is approved for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy –

– Kadmon to Host Conference Call on Monday, July 19, 2021 at 8:00 a.m. ET –

NEW YORK, July 16, 2021 – Kadmon Holdings, Inc. (Nasdaq: KDMN) today announced that the U.S. Food and Drug Administration (FDA) has approved REZUROCK™ (belumosudil) 200 mg once daily (QD) for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy. The FDA granted Breakthrough Therapy designation and Priority Review for REZUROCK and reviewed the New Drug Application (NDA) under the Real-Time Oncology Review (RTOR) pilot program. The FDA approved this NDA six weeks ahead of the Prescription Drug User Fee Act (PDUFA) goal date of August 30, 2021. REZUROCK is the first and only FDA-approved small molecule inhibitor of ROCK2, a signaling pathway that modulates inflammatory responses and fibrotic processes.

“REZUROCK represents a new treatment paradigm for thousands of cGVHD patients, including those with difficult-to-treat manifestations like fibrosis,” said Corey Cutler, MD, MPH, FRCPC, Associate Professor of Medicine at Harvard Medical School and Medical Director, Adult Stem Cell Transplantation Program at the Dana-Farber Cancer Institute. “REZUROCK has shown robust and durable responses across the spectrum of cGVHD and is safe and well tolerated, allowing patients to stay on therapy and achieve meaningful benefit from treatment.”

The FDA approval of REZUROCK is based on safety and efficacy results from ROCKstar (KD025-213), a randomized, open-label, multicenter pivotal trial of REZUROCK in patients with cGVHD who had received two to five prior lines of systemic therapy. There were 65 patients treated with REZUROCK 200 mg taken orally QD. The median time from cGVHD diagnosis was 25.3 months and 48% of patients had four or more organs involved. Patients had cycled through a median of 3 prior lines of systemic therapy and 78% were refractory to their last therapy. REZUROCK 200 mg QD achieved an Overall Response Rate (ORR) of 75% through Cycle 7 Day 1 of treatment (95% Confidence Interval (CI): 63, 85), with 6% achieving a complete response and 69% achieving a partial response. The median time to first response was 1.8 months. Sixty-two percent (62%) of responders did not require new systemic therapy for at least 12 months following response. The median duration of response, calculated from first response to progression, death, or new systemic therapies for chronic GVHD, was 1.9 months. ORR results were supported by clinically meaningful improvement from baseline in the Lee Symptom Scale (LSS) score, a chronic GVHD symptom measurement, in 52% of patients through Cycle 7 Day 1 of treatment.

“Patients receiving REZUROCK reported significant improvements in cGVHD symptoms, showing that not only did treatment result in organ responses, but it also made people feel better. This is so important for a chronic disease with a high symptom burden,” said Stephanie Lee, MD, MPH, Professor at the Fred Hutchinson Cancer Research Center and the University of Washington School of Medicine, and Research Director of the Long-Term Follow-Up Program at Fred Hutchinson.

REZUROCK has been well tolerated and adverse events have been consistent with those expected in patients with advanced cGVHD receiving corticosteroids and/or other immunosuppressants.

“We are proud to introduce REZUROCK as a new treatment that uniquely addresses the underlying inflammatory and fibrotic pathophysiology of chronic GVHD,” said Harlan W. Waksal, MD, President and CEO of Kadmon. “Thank you to the patients, their families and caregivers, who are the center of our focus in achieving this significant milestone. We have built a hematology/oncology-experienced commercial team and we look forward to rapid adoption of REZUROCK for patients in need.”

REZUROCK is expected to be available in the United States by late August 2021.

Kadmon is committed to helping patients with treatment access and support. Kadmon ASSIST™ is a program designed to help and support REZUROCK patients and their caregivers throughout their treatment journey. This program provides reimbursement assistance and savings programs for eligible patients. For more information, please call 1-844-KADMON1 (1-844-523-6661), Monday-Friday, 8:00 a.m.to 8:00 p.m. ET.

The NDA for REZUROCK is part of Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among participating international health authorities.

Conference Call and Webcast

Kadmon will host a conference call on Monday, July 19, 2021 at 8:00 a.m. ET to discuss the FDA approval of REZUROCK.

To participate in the conference call, please dial (866) 762-3021 (domestic) or +1 (703) 925-2661 (international) and reference the conference ID: 5399837.

About cGVHD

cGVHD is a complication that can occur following allogeneic stem cell transplantation, resulting in significant morbidity and mortality. 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 living with cGVHD.

About REZUROCK™ (belumosudil)

REZUROCK™ (belumosudil) is the first and only approved therapy targeting Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response and fibrotic processes. REZUROCK is approved in the United States for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy. For more information, visit www.REZUROCK.com.

Kadmon is also developing belumosudil for the treatment of systemic sclerosis. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of systemic sclerosis.

INDICATIONS AND USAGE

REZUROCK is a kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: Based on findings in animals and its mechanism of action, REZUROCK can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential and males with female partners of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions, including laboratory abnormalities, in patients receiving REZUROCK were infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension.

To report suspected adverse reactions, contact Kadmon at 1-877-377-7862 or the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.

Please visit www.REZUROCK.com to see the full Prescribing Information for REZUROCK.

About Kadmon

Kadmon is a biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. REZUROCK™ (belumosudil), an oral, once-daily, tablet, is approved in the United States for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy. Kadmon's clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies. For more information, please visit www.kadmon.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations regarding REZUROCK™ (belumosudil) as a new available therapy, the timing of commercial availability of REZUROCK in the U.S., the commercial launch of REZUROCK in the U. S. and the potential benefit of our clinical and preclinical development programs for immune and fibrotic diseases as well as immuno-oncology therapies. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target,” “contemplate” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statement contained in this press release, including, without limitation, (i) our ability to commercialize REZUROCK and execute on our marketing plans for any other drugs or indications that may be approved in the future, (ii) risks that REZUROCK revenue, expenses and costs may not be as expected, (iii) risks relating to REZUROCK’s market acceptance, competition, reimbursement and regulatory actions, (iv) risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, including, without limitation, commercial and clinical drug supply chain continuity and the commercial launch of REZUROCK, (v) our ability to obtain and maintain reimbursement for REZUROCK and any approved product and the extent to which patient assistance programs and copay programs are utilized, (vi) our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, (vii) availability and timing of data from our preclinical and clinical trials, which may not support further development of our product candidates, (viii) our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, (ix) actions of regulatory agencies, (x) the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, (xi) competition from other products, (xii) our ability to comply with healthcare regulations and laws, (xiii) our ability to obtain, maintain and enforce our intellectual property rights, (xiv) our ability to maintain and establish strategic agreements and collaborations and the potential benefits of those arrangements and (xv) other risks, including active or potential litigation risks, any or all of which of the foregoing may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and make our investigational drugs and REZUROCK available to patients, and to derive revenue from product sales. More detailed information about us and the risk factors that may affect the realization of our forward-looking statements are set forth in our Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and subsequent filings with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, except as may be required by law. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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