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): June 23, 2020

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
(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 June 23, 2020, Kadmon Holdings, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in a Phase 1 clinical trial evaluating KD033, the Company's anti-PD-L1/IL-15 fusion protein, in patients with metastatic or locally advanced solid tumors.

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 June 23, 2020.

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: June 23, 2020

/s/ Harlan W. Waksal

Harlan W. Waksal
President and Chief Executive Officer

Kadmon Doses First Patient in Phase 1 Clinical Trial of KD033, an Anti-PD-L1/IL-15 Fusion Protein, in Adults with Metastatic or Locally Advanced Solid Tumors

NEW YORK, June 23, 2020 – Kadmon Holdings, Inc. (NYSE: KDMN) today announced that the first patient has been dosed in a Phase 1 clinical trial evaluating KD033, an anti-PD-L1/IL-15 fusion protein, in patients with metastatic or locally advanced solid tumors. KD033 is a novel immunotherapy designed to stimulate innate and adaptive immune responses directed to the tumor microenvironment.

“We are pleased to initiate clinical development of KD033, which has demonstrated encouraging efficacy and durability in a variety of tumor types in preclinical models,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “By directing the anti-tumor activity of IL-15 to the tumor microenvironment, KD033 has the potential to stimulate patients’ immune responses to fight cancer while avoiding systemic toxicities. This study initiation represents an important milestone for Kadmon and our platform of IL-15-containing fusion proteins. We look forward to providing further updates on this trial as they become available.”

Recombinant IL-15 (rIL-15) is an immunostimulatory cytokine that has demonstrated clinical activity in the treatment of several cancers. rIL-15 expands key tumor-fighting cell types, including natural killer (NK), natural killer T (NKT) and memory T cells, without expanding immunosuppressive Treg cells, allowing for robust and durable anti-tumor responses. Clinical use of rIL-15 has been limited by its short half-life and narrow therapeutic window. To address these challenges, Kadmon has developed KD033, which is designed to direct IL-15 activity to the tumor microenvironment of PD-L1-expressing tumors and to achieve a greater therapeutic window. KD033 is designed to promote long-lasting efficacy while reducing systemic exposure of IL-15 to potentially increase safety and tolerability.

In preclinical studies, a single dose of KD033 demonstrated robust in vivo pharmacological activity and inhibited tumor growth across multiple syngeneic mouse models. KD033 also induced T-cell memory, resulting in mice that remained tumor-free following several tumor re-challenges. KD033 demonstrated significant tumor inhibition in animal models that are resistant to approved immunotherapies such as PD-L1, PD-1 or CTLA-4 antibodies.

About the KD033-101 Clinical Trial

KD033-101 is a Phase 1, open-label, dose escalation and dose expansion study investigating the safety and efficacy of KD033 in patients with metastatic or locally advanced solid tumors. The dose escalation phase of the study will evaluate the pharmacokinetics and pharmacodynamics and identify the maximum tolerated dose (MTD) of KD033. The dose expansion phase of the study will enroll approximately 15 patients who have progressed or are refractory to programmed cell death protein 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy to assess safety, efficacy and determine the recommended Phase 2 dose (RP2D) of KD033.

About KD033

KD033 is a novel immunotherapy developed in-house and is fully owned by Kadmon. KD033 combines an anti-PD-L1 antibody with IL-15, a cytokine that expands key tumor-fighting cell types, including natural killer (NK), natural killer T (NKT) and memory T cells, to potentially induce durable responses and inhibit tumor growth. The anti-PD-L1 antibody directs IL-15 activity to the tumor microenvironment, limiting systemic exposure of IL-15 to potentially increase safety and tolerability. KD033 was well tolerated in GLP toxicology studies at clinically relevant doses. KD033 process development and manufacturing was completed through a successful collaboration with Wuxi Biologics and exhibited desired manufacturability and stability criteria.

KD033 is the most advanced candidate from Kadmon's IL-15 fusion protein platform. The Company is developing a portfolio of therapies combining IL-15 with select antibodies for the treatment of cancer.

About Kadmon

Kadmon is a biopharmaceutical company developing innovative products for significant unmet medical needs. Our product pipeline is focused on inflammatory and fibrotic diseases as well as immuno-oncology.

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 impact of COVID-19 on our ability to conduct our business or our clinical trials, (ii) the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; (iii) our ability to advance product candidates into, and successfully complete, clinical trials; (iv) our reliance on the success of our product candidates; (v) the timing or likelihood of regulatory filings and approvals, including an NDA regarding belumosudil (KD025); (vi) our ability to expand our sales and marketing capabilities; (vii) the commercialization of our product candidates, if approved; (viii) the pricing and reimbursement of our product candidates, if approved; (ix) the implementation of our business model, strategic plans for our business, product candidates and technology; (x) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (xi) our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; (xii) costs associated with defending intellectual property infringement, product liability and other claims; (xiii) regulatory developments in the United States, Europe, China, Japan and other jurisdictions; (xiv) estimates of our expenses, future revenues, capital requirements and our needs for additional financing; (xv) the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; (xvi) our ability to maintain and establish collaborations or obtain additional grant funding; (xvii) the rate and degree of market acceptance of our product candidates; (xviii) developments relating to our competitors and our industry, including competing therapies; (xix) our ability to effectively manage our anticipated growth; (xx) our ability to attract and retain qualified employees and key personnel; (xxi) the use of proceeds from our recent public offerings; (xxii) the potential benefits of any of our product candidates being granted orphan drug designation; (xxiii) the future trading price of the shares of our common stock and impact of securities analysts' reports on these prices; and/or (xxiii) other

risks and uncertainties. More detailed information about the Company 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 Kadmon's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 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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