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): May 9, 2019

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 (212) 308-6000

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))

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. ☒

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

ITEM 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Kadmon Holdings, Inc. (the "Company") issued a press release providing an update on upcoming milestones and recent achievements, and announcing its financial and operational results for the three months ended March 31, 2019. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, including Exhibit 99.1 hereto, is being "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of Section 18 of the Exchange Act. The information in this Item 2.02 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit shall be deemed to be "filed," not "furnished," for purposes of the Exchange Act.

Exhibit No.	**Description**
99.1	Press Release issued by Kadmon Holdings, Inc., dated May 9, 2019.

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: May 9, 2019

/s/ Harlan W. Waksal

Harlan W. Waksal
President and Chief Executive Officer

Kadmon Provides Business Update and Reports First Quarter 2019 Financial Results

NEW YORK, May 9, 2019 – Kadmon Holdings, Inc. (NYSE: KDMN) today provided a business update and reported financial and operational results for the first quarter of 2019.

"The advancement of KD025 for the treatment of cGVHD continues to be Kadmon's key priority. We recently held a Type B Breakthrough Therapy meeting with the FDA and remain aligned with the Agency on our registration study design and the broader data package to support a potential New Drug Application," said Harlan W. Waksal, M.D., President and CEO at Kadmon. "We are pleased with the enrollment progress in our ongoing registration study and are on track to complete enrollment in the second half of 2019. By the end of this year, following completion of enrollment, we expect to share guidance on the initial analysis of our registration trial and our regulatory pathway."

Dr. Waksal continued, "Since the start of 2019, we have added three new directors to our Board and appointed a new CFO to further expand our strategic capabilities. Kadmon has the leadership and capital resources in place to continue the advancement of our pipeline of product candidates for major unmet medical needs."

2019 Anticipated Key Clinical Milestones:

KD025

- Complete enrollment in registration trial of KD025 in chronic graft-versus-host disease (cGVHD) in 2H 2019
- Provide guidance on initial analysis of registration trial and regulatory pathway of KD025 in cGVHD in 2H 2019
- Initiate double-blind, placebo-controlled Phase 2 clinical trial of KD025 in systemic sclerosis (scleroderma) in 2Q 2019

KD045

- Initiate clinical trial of KD045, Kadmon's next-generation pan-ROCK inhibitor for the treatment of fibrotic diseases, in 2H 2019

KD033

- Initiate clinical trial of KD033, Kadmon's anti-PD-L1/IL-15 fusion protein for immuno-oncology, in 2H 2019

KD034

- Continue dialogue with the U.S. Food and Drug Administration (FDA) regarding its review and approval of KD034, Kadmon's generic trientine hydrochloride drug candidates, for the treatment of Wilson's disease

Recent Business Highlights

Kadmon strengthened its leadership team with the naming of three new members of the Board of Directors and the addition of a key executive:

- David E. Cohen, M.D., MPH, was appointed to the Board of Directors in February 2019. Dr. Cohen is the Charles C. and Dorothea E. Harris Professor of Dermatology at New York University School of Medicine, where he also serves as Chief of Allergy and Contact Dermatitis, Vice Chairman of Clinical Affairs, and Director of Occupational and Environmental Dermatology.
- Arthur Kirsch has been nominated to stand for election to the Board of Directors at the 2019 Annual Meeting of Stockholders to be held on May 15, 2019. Mr. Kirsch has more than 40 years of experience leading global healthcare research and investment banking operations, including his current role as Senior Advisor and Head of Healthcare at GCA Global, an investment bank.
- Cynthia Schwalm was appointed to the Board of Directors in January 2019. Ms. Schwalm has extensive pharmaceutical industry experience, having held management roles at Johnson & Johnson, Amgen and Eisai, and most recently served as President and CEO of Ipsen North America.
- Steven Meehan was named Executive Vice President, Chief Financial Officer in February 2019. Mr. Meehan, who has served as a member of the Board of Directors at Kadmon since 2017, has over 25 years of financial leadership experience spanning corporate strategy, mergers and acquisitions, capital raising and financial planning and analysis.

Financial Results

First Quarter 2019 Results

Loss from operations for the three months ended March 31, 2019 was $22.7 million, compared to $17.9 million for the same period in 2018.

Research and development expenses for the three months ended March 31, 2019 were $15.0 million, compared to $9.8 million for the same period in 2018. The increase in research and development expenses was primarily related to the development of KD025, our most advanced product candidate, as well as the development of KD045 and KD033.

Selling, general and administrative expenses for the three months ended March 31, 2019 were $7.9 million, compared to $8.3 million for the same period in 2018.

Liquidity and Capital Resources

At March 31, 2019, Kadmon's cash and cash equivalents totaled $99.4 million, compared to $94.7 million at December 31, 2018. In addition, as of March 31, 2019, Kadmon maintained approximately 10.7% ownership of common stock of MeiraGTx Holdings plc, a publicly-traded (Nasdaq: MGTX), clinical-stage gene therapy company.

About KD025

KD025 is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response. Enrollment is ongoing in KD025-213, a registration trial of KD025 in adults with cGVHD who have received at least two prior lines of systemic therapy. The primary endpoint of the study is the Overall Response Rate (ORR), defined as the percentage of patients who meet the 2014 National Institutes of Health (NIH) Consensus Conference overall response criteria of complete or partial response. In October 2018, the FDA granted Breakthrough Therapy Designation to KD025 for the treatment of cGVHD, which was supported by data from a Phase 2 clinical trial of KD025 in cGVHD (KD025-208). In August 2017, the FDA granted Orphan Drug Designation to KD025 for the treatment of cGVHD.

About Kadmon Holdings, Inc.

Kadmon Holdings, Inc. is a fully integrated biopharmaceutical company developing innovative products for significant unmet medical needs. Our product pipeline is focused on autoimmune, 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 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 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) our ability to achieve cost savings and other benefits from our efforts to streamline our operations and to not harm our business with such efforts; (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 (xxiv) 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. 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.

Kadmon Holdings, Inc.
Consolidated Statements of Operations - Unaudited
(in thousands, except per share data)

	Three Months Ended March 31,	
	2019	2018
Revenues		
Net sales	$ 67	$ 274
Other revenue	174	159
Total revenue	241	433
Cost of sales	31	199
Write-down of inventory	—	147
Gross profit	210	87
Operating expenses:		
Research and development	14,991	9,780
Selling, general and administrative	7,946	8,250
Total operating expenses	22,937	18,030
Loss from operations	(22,727)	(17,943)
Total other (income) expense	(26,319)	2,498
Income tax expense	—	—
Net income (loss)	$ 3,592	$ (20,441)
Deemed dividend on convertible preferred stock	515	490
Net income (loss) attributable to common stockholders	$ 3,077	$ (20,931)
Basic net income (loss) per share of common stock	$ 0.02	$ (0.27)
Diluted net income (loss) per share of common stock	$ 0.02	$ (0.27)
Weighted average basic shares of common stock outstanding	126,330,788	78,650,143
Weighted average diluted shares of common stock outstanding	126,406,039	78,650,143

Kadmon Holdings, Inc.
Condensed Consolidated Balance Sheets - Unaudited
(in thousands)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 99,358	$ 94,740
Other current assets	4,406	4,196
Investment, equity securities	60,903	34,075
Right of use lease asset	22,006	—
Other noncurrent assets	11,562	11,650
Total assets	$ 198,235	$ 144,661
Current liabilities	26,677	24,018
Lease liability - noncurrent	22,610	—
Other long term liabilities	415	4,752
Secured term debt – net of current portion and discount	25,325	27,480
Total liabilities	75,027	56,250
Total stockholders' equity	123,208	88,411
Total liabilities and stockholders' equity	$ 198,235	$ 144,661

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