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 7, 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:

☐ 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 2.02 Results of Operations and Financial Condition.

On May 7, 2020, Kadmon Holdings, Inc. issued a press release providing a business update and announcing its financial and operational results for the three months ended March 31, 2020. 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, including Exhibit 99.1 hereto, 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.

Exhibit No.	**Description**
99.1	Press Release issued by Kadmon Holdings, Inc., dated May 7, 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: May 7, 2020

/s/ Harlan W. Waksal

Harlan W. Waksal
President and Chief Executive Officer

Kadmon Provides Business Update and Reports First Quarter 2020 Financial Results

NEW YORK, May 7, 2020 – Kadmon Holdings, Inc. (NYSE: KDMN) today provided a business update and reported financial and operational results for the first quarter of 2020.

"We made encouraging progress this past quarter, having completed our pre-NDA meeting with the FDA. Based on the feedback we have received from the Agency to date, we are confident that our proposed data package will be sufficient to support a submission of KD025 for the treatment of patients with cGVHD in the fourth quarter of this year, as previously guided. We continue to expect to announce topline results from the six-month primary analysis of our pivotal trial of KD025 in cGVHD in the second quarter of 2020, which will include an updated look at Overall Response Rate and safety, as well as initial data on duration of response," said Harlan W. Waksal, M.D., President and CEO of Kadmon.

Dr. Waksal continued, "Although our near-term goal of advancing KD025 in cGVHD remains on target, we are experiencing COVID-19-related delays in enrollment in the ongoing Phase 2 study of KD025 in systemic sclerosis as well as a delay in the initiation of the clinical trial in KD033, our immuno-oncology fusion protein. We continue to monitor the situation at hand in order to attain a better understanding of new timelines within these studies."

Dr. Waksal concluded, "We continue to prioritize the health and safety of our employees and patients as we manage the impact of COVID-19. We have implemented measures including work-from-home directives, while maintaining our operations. In these unprecedented times, the steps we are taking position the Company to continue to advance our pipeline of product candidates."

2020 Anticipated Key Clinical Milestones:

KD025

- Announce topline results (updated Overall Response Rate and safety data as well as initial data on duration of response) from primary analysis of KD025-213, the pivotal trial in chronic graft-versus-host disease (cGVHD), conducted six months after completion of enrollment, in the second quarter of 2020; additional secondary endpoints, including failure-free survival and overall survival, will be submitted for presentation at an upcoming medical meeting
- Submit New Drug Application (NDA) for KD025 in cGVHD to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2020
- Continue enrollment in ongoing Phase 2 clinical trial in systemic sclerosis (KD025-209); enrollment is delayed due to the COVID-19 pandemic

KD033

- Previously guided to initiate clinical trial of KD033, Kadmon's anti-PD-L1/IL-15 fusion protein, in the second quarter of 2020; enrollment is delayed due to the COVID-19 pandemic

KD045

- Continue ongoing Investigational New Drug Application (IND)-enabling activities of KD045, Kadmon's next-generation ROCK inhibitor for the treatment of fibrotic diseases

Financial Results

First Quarter 2020 Results

Loss from operations for the three months ended March 31, 2020 was $16.1 million, compared to $22.7 million for the same period in 2019.

The decrease in loss from operations was primarily due to $6.0 million of license revenue recognized by the Company during the three months ended March 31, 2020 related to the strategic partnership with Meiji Seika Pharma Co., Ltd.

Liquidity and Capital Resources

At March 31, 2020, the Company's cash and cash equivalents totaled $120.0 million, compared to $139.6 million at December 31, 2019. In addition, as of March 31, 2020, the Company held approximately 2.1 million ordinary shares of MeiraGTx Holdings plc (Nasdaq: MGTX), a clinical-stage gene therapy company, with a fair value of $28.2 million.

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. KD025 is being studied in an ongoing pivotal trail in cGVHD as well as an ongoing Phase 2 clinical trial in adults with diffuse cutaneous systemic sclerosis (KD025-209). The FDA has granted Breakthrough Therapy Designation to KD025 for the treatment of patients with cGVHD after failure of two or more prior lines of systemic therapy. The FDA has also granted Orphan Drug Designation to KD025 for the treatment of patients with cGVHD.

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) the impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials; (iv) our reliance on the success of our product candidates; (iv) the timing or likelihood of regulatory filings and approvals, especially in light of the COVID-19 pandemic; (v) our ability to expand our sales and marketing capabilities; (vi) our ability to expand our sales and marketing capabilities; (vii) the commercialization, 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; (xvi) the rate and degree of market acceptance of our product candidates, if approved; (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 expected use of cash and cash equivalents and other sources of liquidity; (xxi) the potential benefits of any of our product candidates being granted orphan drug designation; (xxii) the future trading price of the shares of our common stock and impact of securities analysts' reports on these prices; (xxiii) the future trading price of our holdings of shares of MeiraGTx and our potential inability to sell those securities; (xxiv) our ability to apply unused federal and state net operating loss carryforwards against future taxable income and/or (xxv) 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. 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 share and per share data)

	Three Months Ended March 31,	
	2020	**2019**
Revenues		
Net sales	$ 589	$ 67
Other revenue	6,146	174
Total revenue	6,735	241
Cost of sales	328	31
Write-down of inventory	284	—
Gross profit	6,123	210
Operating expenses:		
Research and development	12,874	14,991
Selling, general and administrative	9,366	7,946
Total operating expenses	22,240	22,937
Loss from operations	(16,117)	(22,727)
Total other (expense) income	(13,180)	26,319
Income tax expense	—	—
Net (loss) income	$ (29,297)	$ 3,592
Deemed dividend on convertible preferred stock	517	515
Net (loss) income attributable to common stockholders	$ (29,814)	$ 3,077
Basic net (loss) income per share of common stock	$ (0.19)	$ 0.02
Diluted net (loss) income per share of common stock	$ (0.19)	$ 0.02
Weighted average basic shares of common stock outstanding	158,031,405	126,330,788
Weighted average diluted shares of common stock outstanding	158,031,405	126,406,039

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 120,046	$ 139,597
Other current assets	4,588	3,010
Investment, equity securities	28,194	41,997
Right of use lease asset	18,782	19,651
Other noncurrent assets	10,167	10,543
Total assets	$ 181,777	$ 214,798
Current liabilities	23,818	28,742
Lease liability - noncurrent	18,732	19,759
Other long term liabilities	461	562
Total liabilities	43,011	49,063
Total stockholders' equity	138,766	165,735
Total liabilities and stockholders' equity	$ 181,777	$ 214,798

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