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): August 6, 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 **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	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 August 6, 2020, Kadmon Holdings, Inc. issued a press release providing a business update and announcing its financial and operational results for the three and six months ended June 30, 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 August 6, 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.

Date: August 6, 2020

Kadmon Holdings, Inc.

/s/ Harlan W. Waksal

Harlan W. Waksal
President and Chief Executive Officer

Kadmon Provides Business Update and Reports Second Quarter 2020 Financial Results

NEW YORK, August 6, 2020 – Kadmon Holdings, Inc. (NYSE: KDMN) today provided a business update and reported financial and operational results for the second quarter of 2020.

"Following positive topline results from the primary analysis of the ROCKstar pivotal trial of belumosudil in cGVHD announced in May 2020, we have had an extremely busy and productive quarter. We are preparing our New Drug Application for belumosudil, which remains on track for submission in the fourth quarter of this year," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We believe the ROCKstar data continue to demonstrate the promise of belumosudil in cGVHD, and as such we are scaling up our launch preparation activities in anticipation of potential approval. Following the raise of $50 million this quarter through our At-The-Market facility, we are well capitalized through the NDA filing, approval and launch of belumosudil."

Dr. Waksal continued, "Furthermore, we were pleased to announce this quarter that the first patient was dosed in a Phase 1 clinical trial of KD033, our novel anti-PD-L1/IL-15 immuno-oncology fusion protein, in patients with metastatic or locally advanced solid tumors. This is an important milestone for our biologics platform and we look forward to sharing key updates as the trial advances."

Upcoming Milestones:

Belumosudil (KD025)

- Submit New Drug Application (NDA) for belumosudil in chronic graft-versus-host disease (cGVHD) to the U.S. Food and Drug Administration (FDA) in Q4 2020; the FDA has accepted belumosudil for review under its Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible

- Continue ongoing discussions with the European Medicines Agency (EMA) to determine a regulatory path forward for belumosudil in cGVHD; the Company plans to share 12-month data from the ROCKstar pivotal trial with the EMA, which will include key secondary endpoints such as Overall Survival and Failure-Free Survival; the Company expects to share an update on the path forward for belumosudil in Europe in 1H 2021

- Continue enrollment in ongoing placebo-controlled Phase 2 clinical trial in diffuse cutaneous systemic sclerosis (KD025-209); enrollment is delayed due to the COVID-19 pandemic

- Initiate small (12-15 patient), open-label Phase 2 clinical trial of belumosudil in patients with diffuse cutaneous systemic sclerosis in Q1 2021

KD033

- Continue enrollment in ongoing dose-escalation Phase 1 clinical trial of KD033, Kadmon's anti-PD-L1/IL-15 fusion protein, in patients with metastatic or locally advanced solid tumors

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

Second Quarter 2020 Results

Loss from operations for the three and six months ended June 30, 2020 was $26.9 million and $43.0 million, respectively, compared to $24.8 million and $47.6 million for the same periods in 2019.

The decrease in loss from operations for the six months ended June 30, 2020 as compared to 2019 was primarily due to $6.0 million of license revenue recognized by the Company during the six months ended June 30, 2020 related to the strategic partnership with Meiji Seika Pharma Co., Ltd.

The increase in loss from operations for the three months ended June 30, 2020 as compared to 2019 was primarily attributable to increased expenses related to preparation for the potential launch of belumosudil.

Liquidity and Capital Resources

At June 30, 2020, the Company's cash and cash equivalents totaled $169.8 million, compared to $139.6 million at December 31, 2019. The increase reflects $50.0 million in gross proceeds the Company accessed through its At-The-Market (ATM) facility along with $15.5 million in non-dilutive financing the Company accessed through the divestiture of 1.1 million ordinary shares of MeiraGTx Holdings plc; both transactions took place in May 2020. As of June 30, 2020, the Company held approximately 1.0 million ordinary shares of MeiraGTx Holdings plc, a clinical-stage gene therapy company. The increase in cash and cash equivalents related to these transactions was partially offset by cash used in operating activities of $37.5 million during the six months ended June 30, 2020.

About ROCKstar

ROCKstar (KD025-213) is an ongoing open-label trial of belumosudil (KD025) in adults and adolescents with cGVHD who have received at least two prior lines of systemic therapy. Patients were randomized to receive belumosudil (KD025) at 200 mg QD or 200 mg BID, enrolling 66 patients per arm. The primary endpoint of the study is Overall Response Rate (ORR). Statistical significance is achieved if the lower bound of the 95% CI of ORR exceeds 30%. The ORR endpoint was met at the interim analysis, conducted two months after completion of enrollment. At the study's primary analysis, conducted six months after completion of enrollment, belumosudil achieved ORRs of 73% and 74% in the respective arms. Kadmon plans to submit results from the ROCKstar primary analysis for presentation at an upcoming scientific meeting.

About Belumosudil (KD025)

Belumosudil (KD025) is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response. The FDA has granted Breakthrough Therapy Designation for belumosudil for the treatment of patients with cGVHD who have received at least two prior lines of systemic therapy. The FDA has also granted Orphan Drug Designation to belumosudil for the treatment of cGVHD. The FDA has accepted belumosudil for review under its Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. Belumosudil is also being studied in an ongoing Phase 2 clinical trial in adults with diffuse cutaneous systemic sclerosis (KD025-209).

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 and on various government agencies who we interact with and/or are governed by; (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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues				
Net sales	$ 299	$ 47	$ 888	$ 114
Other revenue	149	179	6,295	353
Total revenue	448	226	7,183	467
Cost of sales	162	45	490	76
Write-down of inventory	622	932	906	932
Gross profit	(336)	(751)	5,787	(541)
Operating expenses:				
Research and development	16,516	15,108	29,390	30,099
Selling, general and administrative	10,068	8,981	19,434	16,927
Total operating expenses	26,584	24,089	48,824	47,026
Loss from operations	(26,920)	(24,840)	(43,037)	(47,567)
Total other (expense) income	(232)	34,000	(13,412)	60,319
Income tax expense	—	—	—	—
Net (loss) income	$ (27,152)	$ 9,160	$ (56,449)	$ 12,752
Deemed dividend on convertible preferred stock	518	508	1,035	1,023
Net (loss) income attributable to common stockholders	$ (27,670)	$ 8,652	$ (57,484)	$ 11,729
Basic net (loss) income per share of common stock	$ (0.17)	$ 0.07	$ (0.36)	$ 0.09
Diluted net (loss) income per share of common stock	$ (0.17)	$ 0.07	$ (0.36)	$ 0.09
Weighted average basic shares of common stock outstanding	162,416,059	129,080,221	161,101,923	127,713,099
Weighted average diluted shares of common stock outstanding	162,416,059	129,090,983	161,101,923	127,750,765

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

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 169,803	$ 139,597
Other current assets	3,151	3,010
Investment, equity securities	12,492	41,997
Right of use lease asset	17,902	19,651
Other noncurrent assets	9,896	10,543
Total assets	$ 213,244	$ 214,798
Current liabilities	30,138	28,742
Lease liability - noncurrent	17,689	19,759
Other long term liabilities	2,160	562
Total liabilities	49,987	49,063
Total stockholders' equity	163,257	165,735
Total liabilities and stockholders' equity	$ 213,244	$ 214,798

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