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): November 5, 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	Nasdaq Global Select Market

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 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 2.02 Results of Operations and Financial Condition.

On November 5, 2020, Kadmon Holdings, Inc. issued a press release providing a business update and announcing its financial and operational results for the three and nine months ended September 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 November 5, 2020.
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: November 5, 2020

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

Kadmon Provides Business Update and Reports Third Quarter 2020 Financial Results

NEW YORK, November 5, 2020 – Kadmon Holdings, Inc. (Nasdaq: KDMN) today provided a business update and reported financial and operational results for the third quarter of 2020.

"The submission of our belumosudil New Drug Application to the FDA represents a significant achievement for Kadmon and advances our efforts to make this therapy available to patients living with chronic GVHD," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We look forward to presenting 12-month safety, efficacy and durability data from our ongoing ROCKstar pivotal trial of belumosudil at the ASH Annual Meeting in December 2020."

Dr. Waksal continued, "Beyond cGVHD, we were pleased to announce that the FDA granted Orphan Designation to belumosudil for the treatment of systemic sclerosis, currently in Phase 2 clinical development. Additionally, we continue to enroll patients with metastatic or locally advanced solid tumors in our Phase 1 clinical trial of KD033, our novel anti-PD-L1/IL-15 immuno-oncology fusion protein. We successfully completed enrollment in the first cohort of this trial; enrollment in the second cohort is ongoing. I am thrilled with the progress we are making across our clinical programs and look forward to sharing updates as we achieve new milestones."

Upcoming Milestones:

Belumosudil (KD025)

- Present 12-month data from ROCKstar pivotal trial at the American Society of Hematology (ASH) Annual Meeting on December 6, 2020; the presentation will include updated efficacy and safety data and key secondary endpoints including duration of response, Failure-Free Survival, steroid dose reductions and quality-of-life improvements

- Continue ongoing dialogue with the U.S. Food and Drug Administration (FDA) as they review the New Drug Application (NDA) under their 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 progressing belumosudil commercial launch readiness activities in anticipation of potential FDA approval in 2021

- 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); the Company continues to work with sites and trial coordinators to facilitate patient enrollment amid 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

- The first 3-patient dose cohort was successfully completed in the 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; enrollment is ongoing in the next dose level (cohort 2)

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

Third Quarter 2020 Results

Loss from operations for the three and nine months ended September 30, 2020 was $28.0 million and $71.0 million, respectively, compared to $23.2 million and $70.8 million for the same periods in 2019.

The increase in loss from operations for the three months ended September 30, 2020 as compared to 2019 was primarily due to an increase in development costs for belumosudil.

Liquidity and Capital Resources

At September 30, 2020, the Company's cash, cash equivalents and marketable debt securities totaled $150.5 million, compared to $139.6 million at December 31, 2019. The increase primarily reflects $50.0 million in gross proceeds the Company accessed through its At-The-Market (ATM) facility in May 2020 along with $19.8 million in non-dilutive financing the Company accessed through the divestiture of 1.4 million ordinary shares of MeiraGTx Holdings plc during the nine months ended September 30, 2020. As of September 30, 2020, the Company held approximately 0.7 million ordinary shares of MeiraGTx Holdings plc, a clinical-stage gene therapy company.

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 and pro-fibrotic processes. The Company has submitted an NDA for belumosudil for the treatment of patients with cGVHD and the NDA is being reviewed under the FDA's RTOR pilot program. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy. The FDA has also granted Orphan Drug Designation to belumosudil for the treatment of cGVHD. In addition, belumosudil is in Phase 2 clinical development in patients with diffuse cutaneous systemic sclerosis (SSc). The FDA has granted Orphan Drug Designation to belumosudil for the treatment of systemic sclerosis.

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, including the acceptance of our NDA for belumosudil, 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) our ability to apply unused federal and state net operating loss carryforwards against future taxable income and/or (xxiv) 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues				
Net sales	$ 339	$ 50	$ 1,227	$ 164
Other revenue	151	176	6,446	529
Total revenue	490	226	7,673	693
Cost of sales	214	73	704	149
Write-down of inventory	148	—	1,054	932
Gross profit	128	153	5,915	(388)
Operating expenses:				
Research and development	17,268	13,227	46,658	43,326
Selling, general and administrative	10,865	10,174	30,299	27,101
Total operating expenses	28,133	23,401	76,957	70,427
Loss from operations	(28,005)	(23,248)	(71,042)	(70,815)
Total other income (expense)	3,399	(39,147)	(10,013)	21,172
Income tax expense	—	—	—	—
Net loss	$ (24,606)	$ (62,395)	$ (81,055)	$ (49,643)
Deemed dividend on convertible preferred stock	543	517	1,578	1,540
Net loss attributable to common stockholders	$ (25,149)	$ (62,912)	$ (82,633)	$ (51,183)
Basic and diluted net loss per share of common stock	$ (0.15)	$ (0.49)	$ (0.50)	$ (0.40)
Weighted average basic and diluted shares of common stock outstanding	169,310,056	128,225,469	165,107,295	128,360,618

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and marketable debt securities	$ 150,463	$ 139,597
Other current assets	2,641	3,010
Investment, equity securities	9,238	41,997
Right of use lease asset	17,013	19,651
Other noncurrent assets	9,634	10,543
Total assets	$ 188,989	$ 214,798
Current liabilities	28,160	28,742
Lease liability - noncurrent	16,631	19,759
Other long term liabilities	2,839	562
Total liabilities	47,630	49,063
Total stockholders' equity	141,359	165,735
Total liabilities and stockholders' equity	$ 188,989	$ 214,798

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