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 5, 2021

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 August 5 2021, Kadmon Holdings, Inc. (the "Company") issued a press release providing a business update and announcing its financial and operational results for the three and six months ended June 30, 2021 (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 2.02.

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 5, 2021.
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: August 5, 2021

/s/ Harlan W. Waksal
Harlan W. Waksal, M.D.
President and Chief Executive Officer

Kadmon Provides Business Update and Reports Second Quarter 2021 Financial Results

NEW YORK, August 5, 2021 – Kadmon Holdings, Inc. (Nasdaq: KDMN) today provided a business update and reported financial and operational results for the second quarter of 2021.

"The recent U.S. FDA approval of REZUROCK marked a transformative event for Kadmon and for patients living with cGVHD. REZUROCK represents a paradigm shift in the cGVHD treatment landscape by uniquely addressing both the immune and fibrotic components of the disease," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We look forward to bringing this meaningful new therapy to patients in the U.S. by the end of this month."

Dr. Waksal added, "Our momentum continues as we advance our portfolio of product candidates. Initial data from our open-label, Phase 2 trial of belumosudil for the treatment of systemic sclerosis is anticipated by year-end 2021. The recent positive initial safety data presented at ASCO on KD033, our anti-PD-L1/IL-15 fusion protein, supports our confidence in the therapeutic potential of IL-15 for cancer. We look forward to sharing additional clinical data from this trial in the fourth quarter of 2021."

2021 Program Updates and Milestones:

REZUROCK™ (belumosudil)

- On July 16, 2021, the U.S. Food and Drug Administration (FDA) approved REZUROCK™ (belumosudil) for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy:
  - Commercial launch activities are underway, with a focus on generating awareness of REZUROCK's differentiated clinical value and facilitating market access
  - Experienced hematology/oncology sales team and account directors are fully trained and have begun engaging with healthcare providers at the top 100 transplant centers, where ~90% of patients are treated
  - REZUROCK availability is anticipated by late August through a network of rare hematology/oncology specialty pharmacies and distributors
  - Kadmon launched Kadmon ASSIST™, a comprehensive suite of patient financial and hub support services, including dedicated nurse practitioners on call to facilitate patient education and a successful clinical experience
  - Kadmon announced on August 4 that the National Comprehensive Cancer Network (NCCN) added REZUROCK tablets to its Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation (HCT) in the Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host Disease in the United States.
  - Results from the pivotal ROCKstar clinical trial of REZUROCK for the treatment of cGVHD were published in the journal *Blood*; available online here

Clinical

Belumosudil in SSc (systemic sclerosis)

- Present initial data from the open-label Phase 2 clinical trial of belumosudil in patients with SSc (KD025-215) by year-end 2021
- Continue enrollment in ongoing placebo-controlled Phase 2 clinical trial in SSc (KD025-209)

KD033

- Enrollment is ongoing in Cohort 4 (100 µg/kg) in the 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 (KD033-101)
- Initial safety data presented at ASCO 2021 demonstrated that KD033 has been well tolerated at doses up to 50 µg/kg, with no dose-limiting toxicities reported
- The Company plans to present additional clinical data from KD033-101 in the fourth quarter of 2021

Financial Results

Second Quarter 2021 Results

Loss from operations for the three and six months ended June 30, 2021 was $32.0 million and $59.4 million, respectively, compared to $26.9 million and $43.0 million for the same period in 2020. The six months ended June 30, 2020 included $6.0 million in one-time license revenues related to the Meiji strategic partnership.

The $5.6 million and $11.2 million increase in operating expenses for the three and six months ended June 30, 2021, respectively, as compared to 2020 was primarily related to belumosudil commercial launch readiness activities, non-cash stock compensation expenses and direct external research and development costs of developing our preclinical product candidates from our immuno-oncology platform.

Liquidity, Capital Resources and Cash Runway

At June 30, 2021, the Company's cash, cash equivalents and marketable debt securities totaled $270.5 million, compared to $123.9 million at December 31, 2020. The Company expects its current financial position to be sufficient to fund its operations and capital expenditures into 2023.

About REZUROCK™ (belumosudil)

REZUROCK™ (belumosudil) is the first and only approved therapy targeting Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response and pro-fibrotic processes. REZUROCK is approved in the United States for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy. For more information, visit www.REZUROCK.com.

Kadmon is also developing belumosudil for the treatment of systemic sclerosis. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of systemic sclerosis.

About Kadmon

Kadmon is a biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. REZUROCK™ (belumosudil), an oral, once-daily, tablet, is approved in the United States for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy. Kadmon's clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies. For more information, please visit the Company's website at www.kadmon.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations regarding REZUROCK™ (belumosudil) as a new available therapy, the timing of commercial availability of REZUROCK in the U.S., the commercial launch of REZUROCK in the U. S., the degree the NCCN Guidelines® influence the best course of treatment and supportive care for people living with cGVHD, and the potential benefit of our clinical and preclinical development programs for immune and fibrotic diseases as well as immuno-oncology therapies. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," "contemplate" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statement contained in this press release, including, without limitation, (i) our ability to commercialize REZUROCK and execute on our marketing plans for any other drugs or indications that may be approved in the future, (ii) risks that REZUROCK revenue, expenses and costs may not be as expected, (iii) risks relating to REZUROCK's market acceptance, competition, reimbursement and regulatory actions, (iv) risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, including, without limitation, commercial and clinical drug supply chain continuity and the commercial launch of REZUROCK, (v) our ability to obtain and maintain reimbursement for REZUROCK and any approved product and the extent to which patient assistance programs and copay programs are utilized, (vi) our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, (vii) availability and timing of data from our preclinical and clinical trials, which may not support further development of our product candidates, (viii) our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, (ix) actions of regulatory agencies, (x) the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, (xi) competition from other products, (xii) our ability to comply with healthcare regulations and laws, (xiii) our ability to obtain, maintain and enforce our intellectual property rights, (xiv) our ability to maintain and establish strategic agreements and collaborations and the potential benefits of those arrangements and (xv) other risks, including active or potential litigation risks, any or all of which of the foregoing may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and make our investigational drugs and REZUROCK available to patients, and to derive revenue from product sales. More detailed information about us and the risk factors that may affect the realization of our forward-looking statements are set forth in our Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and subsequent filings with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, except as may be required by law. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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,	
	2021	2020	2021	2020
Revenues				
Net sales	$ 24	$ 299	$ 384	$ 888
Other revenue	173	149	377	6,295
Total revenue	197	448	761	7,183
Cost of sales	11	162	107	490
Write-down of inventory	—	622	—	906
Gross profit	186	(336)	654	5,787
Operating expenses:				
Research and development	18,525	16,516	33,799	29,390
Selling, general and administrative	13,656	10,068	26,252	19,434
Total operating expenses	32,181	26,584	60,051	48,824
Loss from operations	(31,995)	(26,920)	(59,397)	(43,037)
Total other income (expense)	1,650	(232)	674	(13,412)
Income tax expense	—	—	—	—
Net loss	$ (30,345)	$ (27,152)	$ (58,723)	$ (56,449)
Deemed dividend on convertible preferred stock	543	518	1,086	1,035
Net loss attributable to common stockholders	$ (30,888)	$ (27,670)	$ (59,809)	$ (57,484)
Basic and diluted net loss per share of common stock	$ (0.18)	$ (0.17)	$ (0.35)	$ (0.36)
Weighted average basic and diluted shares of common stock outstanding	171,967,623	162,416,059	171,829,335	161,101,923

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable debt securities	$ 270,494	$ 123,858
Other current assets	5,449	2,879
Investment, equity securities	10,815	10,564
Right of use lease asset	14,504	16,112
Other noncurrent assets	9,018	9,297
Total assets	$ 310,280	$ 162,710
Current liabilities	30,318	29,471
Lease liability - noncurrent	13,359	15,579
Other long term liabilities	233,148	1,637
Total liabilities	276,825	46,687
Total stockholders' equity	33,455	116,023
Total liabilities and stockholders' equity	$ 310,280	$ 162,710

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