UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For transition period from _____ to _____.

Commission File Number: 001-37841

Kadmon Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3576929**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
450 East 29th Street, New York, NY	**10016**
(Address of principal executive offices)	(Zip Code)

(833) 900-5366
(Registrant's telephone number, including area code)

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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer x Smaller reporting company x 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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

The number of shares of the registrant's common stock outstanding as of August 2, 2021 was 172,350,363.

Kadmon Holdings, Inc.

Quarterly Report Form 10-Q

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q may be forward-looking statements. Statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, including, among others, statements regarding future expenditures, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “would,” “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, the following:

- our ability to commercialize REZUROCK™ (belumosudil) and execute on our marketing plans for any other drugs or indications that may be approved in the future;
- risks that REZUROCK revenue, expenses and costs may not be as expected;
- risks relating to REZUROCK’s market acceptance, competition, reimbursement and regulatory actions;
- 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;
- our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers;
- the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- 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, on various government agencies who we interact with and/or are governed by and commercial and clinical drug supply chain continuity and the commercial launch of REZUROCK;
- the timing or likelihood of regulatory filings and approvals, especially in light of the COVID-19 pandemic;
- the benefits of U.S. Food and Drug Administration (“FDA”) designations such as the Orphan Drug Designation;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product and product candidates and technology;
- cost associated with defending or enforcing, if any, intellectual property infringement, misappropriation or other intellectual property violation, product liability and other claims;
- regulatory and governmental policy developments in the United States, Europe and other jurisdictions;
- our ability to maintain and establish strategic agreements and collaborations and their potential benefits;
- developments relating to our competitors and our industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- statements and estimates regarding future revenue, hiring plans, operating expenses, capital expenditures, capital requirements, needs for additional financing and share performance;
- litigation, including costs associated with prosecuting or defending pending or threatened claims and any adverse outcomes or settlements not covered by insurance;
- our expected use of cash, cash equivalents and marketable debt securities and other sources of liquidity;
- our ability to manage our liquidity needs, including our ability to raise additional capital, to fund our operations or repay our debt obligations;
- the future trading price of the shares of our common stock;
- our ability to apply unused federal and state net operating loss carryforwards against future taxable income; and/or
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions, and we may not actually achieve the plans, intentions or expectations included in our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by law, we disclaim any duty to update any forward looking statements, whether as a result of new information, future events or otherwise.

PART I. FINANCIAL INFORMATION

Kadmon Holdings, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 61,881	$ 74,423
Marketable debt securities, available-for-sale	208,613	49,435
Accounts receivable, net	1,543	695
Inventories, net	12	102
Prepaid expenses and other current assets	3,894	2,082
Investment, equity securities	10,815	10,564
Total current assets	286,758	137,301
Fixed assets, net	1,012	1,287
Right of use lease asset	14,504	16,112
Goodwill	3,580	3,580
Restricted cash	2,117	2,117
Investment, at cost	2,300	2,300
Other noncurrent assets	9	13
Total assets	$ 310,280	$ 162,710
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,559	$ 10,933
Accrued expenses	14,544	11,534
Term debt - current	—	1,699
Lease liability - current	4,482	4,223
Warrant liabilities	733	1,082
Total current liabilities	30,318	29,471
Lease liability - noncurrent	13,359	15,579
Deferred tax liability	278	278
Term debt - noncurrent	—	1,359
Convertible notes, net	232,870	—
Total liabilities	276,825	46,687
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; 28,708 shares issued and outstanding at June 30, 2021 and December 31, 2020.	45,641	44,555
Common stock, $0.001 par value; 400,000,000 shares authorized at June 30, 2021 and December 31, 2020; 171,985,864 and 171,530,045 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	171	171
Additional paid-in capital	491,721	515,429
Accumulated deficit	(503,913)	(444,104)
Accumulated other comprehensive loss	(165)	(28)
Total stockholders' equity	33,455	116,023
Total liabilities and stockholders' equity	$ 310,280	$ 162,710

See accompanying notes to consolidated financial statements (unaudited)

Kadmon Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(in thousands, except share and per share amounts)

	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)
Other income (expense):				
Interest income	1,120	128	1,720	594
Interest expense	(2,497)	(5)	(3,726)	(5)
Realized gain on equity securities	—	15,510	—	15,510
Unrealized gain (loss) on equity securities	747	(15,702)	251	(29,505)
PPP Loan forgiveness	3,091	—	3,091	—
Other income (expense)	(811)	(163)	(662)	(6)
Total other income (expense)	1,650	(232)	674	(13,412)
Loss before income tax expense	(30,345)	(27,152)	(58,723)	(56,449)
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
Other comprehensive (income) loss:				
Net unrealized (gain) loss on available-for-sale securities	(105)	—	137	—
Other comprehensive (income) loss	(105)	—	137	—
Comprehensive loss attributable to common stockholders	$ (30,783)	$ (27,670)	$ (59,946)	$ (57,484)

See accompanying notes to consolidated financial statements (unaudited)

Kadmon Holdings, Inc.
Consolidated Statements of Stockholders' Equity (unaudited)
(in thousands, except share amounts)

For the Three Months Ended June 30, 2021

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, April 1, 2021	28,708	$ 45,098	171,816,945	$ 171	$ 487,230	$ (270)	$ (473,025)	$ 59,204
Share-based compensation expense	—	—	—	—	3,948	—	—	3,948
Common stock issued under ESPP plan	—	—	94,420	—	313	—	—	313
Common stock issued for option exercises	—	—	74,499	—	230	—	—	230
Beneficial conversion feature on convertible preferred stock	—	108	—	—	—	—	(108)	—
Accretion of dividends on convertible preferred stock	—	435	—	—	—	—	(435)	—
Other comprehensive income	—	—	—	—	—	105	—	105
Net loss	—	—	—	—	—	—	(30,345)	(30,345)
Balance, June 30, 2021	28,708	$ 45,641	171,985,864	$ 171	$ 491,721	$ (165)	$ (503,913)	$ 33,455

For the Three Months Ended June 30, 2020

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, April 1, 2020	28,708	$ 42,950	159,830,774	$ 160	$ 458,539	$ —	$ (362,883)	$ 138,766
Share-based compensation expense	—	—	—	—	2,621	—	—	2,621
Common stock issued in public offering, net	—	—	11,060,786	11	48,430	—	—	48,441
Common stock issued under ESPP plan	—	—	98,840	—	216	—	—	216
Common stock issued for option exercises	—	—	106,667	—	365	—	—	365
Beneficial conversion feature on convertible preferred stock	—	104	—	—	—	—	(104)	—
Accretion of dividends on convertible preferred stock	—	414	—	—	—	—	(414)	—
Net loss	—	—	—	—	—	—	(27,152)	(27,152)
Balance, June 30, 2020	28,708	$ 43,468	171,097,067	$ 171	$ 510,171	$ —	$ (390,553)	$ 163,257

See accompanying notes to consolidated financial statements (unaudited)

Kadmon Holdings, Inc.
Consolidated Statements of Stockholders' Equity (unaudited)
(in thousands, except share amounts)

For the Six Months Ended June 30, 2021

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, January 1, 2020	28,708	$ 44,555	171,530,045	$ 171	$ 515,429	$ (28)	$ (444,104)	$ 116,023
Share-based compensation expense	—	—	—	—	7,621	—	—	7,621
Common stock issued under ESPP plan	—	—	94,420	—	313	—	—	313
Common stock issued for option exercises	—	—	361,399	—	1,358	—	—	1,358
Payments for capped call transactions	—	—	—	—	(33,000)	—	—	(33,000)
Beneficial conversion feature on convertible preferred stock	—	217	—	—	—	—	(217)	—
Accretion of dividends on convertible preferred stock	—	869	—	—	—	—	(869)	—
Other comprehensive loss	—	—	—	—	—	(137)	—	(137)
Net loss	—	—	—	—	—	—	(58,723)	(58,723)
Balance, June 30, 2021	28,708	$ 45,641	171,985,864	$ 171	$ 491,721	$ (165)	$ (503,913)	$ 33,455

For the Six Months Ended June 30, 2020

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, January 1, 2020	28,708	$ 42,433	159,759,996	$ 160	$ 456,211	$ —	$ (333,069)	$ 165,735
Share-based compensation expense	—	—	—	—	4,658	—	—	4,658
Common stock issued in public offering, net	—	—	11,060,786	11	48,430	—	—	48,441
Common stock issued under ESPP plan	—	—	98,840	—	216	—	—	216
Common stock issued for warrant exercises	—	—	2,777	—	7	—	—	7
Common stock issued for option exercises	—	—	174,668	—	649	—	—	649
Beneficial conversion feature on convertible preferred stock	—	207	—	—	—	—	(207)	—
Accretion of dividends on convertible preferred stock	—	828	—	—	—	—	(828)	—
Net loss	—	—	—	—	—	—	(56,449)	(56,449)
Balance, June 30, 2020	28,708	$ 43,468	171,097,067	$ 171	$ 510,171	$ —	$ (390,553)	$ 163,257

See accompanying notes to consolidated financial statements (unaudited)

Kadmon Holdings, Inc.
Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (58,723)	$ (56,449)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premium and discounts on available-for-sale securities	1,479	—
Amortization of debt discount	476	—
Depreciation and amortization of fixed assets	520	845
Non-cash operating lease cost	1,848	1,749
Write-down of inventory	—	906
Share-based compensation	7,621	4,658
Change in fair value of warrant liabilities	(349)	133
Net unrealized (gain) loss on equity securities	(251)	13,995
Gain on settlement of obligation	(3,549)	(128)
Changes in operating assets and liabilities:		
Accounts receivable, net	(848)	558
Inventories, net	90	(382)
Prepaid expenses and other assets	(1,808)	(1,142)
Accounts payable	(374)	2,513
Lease liability	(2,201)	(1,959)
Accrued expenses	3,501	(2,811)
Net cash used in operating activities	(52,568)	(37,514)
Cash flows from investing activities:		
Purchases of investment debt securities	(183,137)	—
Maturities of investment debt securities	22,343	—
Purchases of fixed assets	(245)	(160)
Proceeds from sale of equity securities	—	15,510
Net cash (used in) provided by investing activities	(161,039)	15,350
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	—	48,441
Proceeds from issuance of term debt	—	3,058
Proceeds from issuance of convertible notes, net of issuance costs	232,394	—
Payments for capped call transactions	(33,000)	—
Proceeds from exercise of options and warrants	1,358	656
Proceeds from issuance of ESPP shares	313	216
Net cash provided by financing activities	201,065	52,371
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,542)	30,207
Cash, cash equivalents and restricted cash, beginning of period	76,540	141,713
Cash, cash equivalents and restricted cash, end of period	$ 63,998	$ 171,920
Components of cash, cash equivalents and restricted cash		
Cash and cash equivalents	61,881	169,803
Restricted cash	2,117	2,117
Total cash, cash equivalents and restricted cash	63,998	171,920
Non-cash investing and financing activities:		
Beneficial conversion feature on convertible preferred stock	217	207
Accretion of dividends on convertible preferred stock	869	828
PPP loan forgiveness	3,091	—
Operating lease liabilities arising from obtaining right-of-use assets	240	—
Operating cash flows paid for amounts included in the measurement of lease liabilities	2,447	2,397
Unpaid fixed asset additions	—	118

See accompanying notes to consolidated financial statements (unaudited)

Kadmon Holdings, Inc.

Notes to Consolidated Financial Statements (unaudited)

1. Organization

The Company

Kadmon Holdings, Inc. (together with its subsidiaries, "Kadmon" or "Company") is a biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address significant unmet medical needs, with a near-term clinical focus on immune and fibrotic diseases as well as immuno-oncology. The Company leverages its multi-disciplinary research and development team members to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing its small molecule and biologics platforms.

In July 2021, the U.S. Food and Drug Administration ("FDA") approved REZUROCK™ (belumosudil) 200 mg once daily ("QD") 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. See Note 14 for additional information.

COVID-19 Update

The ongoing COVID-19 pandemic has severely impacted global economic activity and caused significant volatility in financial markets. While the Company's financial condition, results of operations, cybersecurity and liquidity have not been materially impacted by the direct effects of the pandemic, the COVID-19 pandemic continues to evolve. The Company is continuing to monitor developments with respect to the COVID-19 pandemic and to make adjustments as needed to assist in protecting the safety of the Company's employees and communities while continuing business activities. To date, implementation of these measures has not required material expenditures or significantly impacted these unaudited financial statements. The Company is continuing to monitor the potential impacts of COVID-19 on its operations and those of its partners, suppliers, customers, and regulators, including commercial and clinical drug supply chain continuity and commercial launch of REZUROCK.

Notwithstanding the foregoing, the Company cannot precisely predict the impact that the COVID-19 pandemic will have in the future due to numerous uncertainties, including the severity of the disease and its variants, the duration of the pandemic, actions that may be taken by governmental authorities, the impact to the business of potential variations or disruptions in the Company's supply chain. The Company will continue to closely monitor and evaluate the nature and extent of the impact of the COVID-19 pandemic to its business, consolidated results of operations, and financial condition.

Liquidity

The Company maintained cash, cash equivalents and marketable debt securities of $270.5 million at June 30, 2021. The Company had an accumulated deficit of $503.9 million and working capital of $256.4 million at June 30, 2021. On February 16, 2021, the Company issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"), pursuant to an Indenture dated February 16, 2021, between the Company and U.S. Bank National Association, as trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. On February 10, 2021, concurrently with the pricing of the Notes, the Company entered into privately negotiated capped call transactions (the "Capped Call Transactions") with certain financial institutions. The Company used approximately $33.0 million of the net proceeds from the Notes offering to pay for the cost of the Capped Call Transactions (Note 5). The net proceeds from the offering were $199.4 million after deducting issuance costs and the cost of Capped Call Transactions.

Based on the Company's expectations for revenue, operating expenses, and its cash, cash equivalents and marketable debt securities available on hand at June 30, 2021, the Company believes it will be able to advance its commercial launch efforts for REZUROCK ™ (belumosudil), advance certain of its other pipeline product candidates, including KD033, and provide for other working capital purposes. Although cash, cash equivalents and marketable debt securities available at June 30, 2021 is expected to execute the Company's current business plans, it may not be sufficient to enable the Company to meet its long-term expected plans. The Company has sustained operating losses for the majority of its corporate history and the Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations.

The Company's future liquidity needs and ability to address those needs will be largely determined by the success of operations in regard to the successful commercialization of its product and the progression of its product candidates in the future, scope and magnitude of its commercial expenses and key development and regulatory events and its decisions in the future. Management's plans may include continuing to finance operations through the issuance of debt and sale of additional equity securities, monetization of assets, and expanding the Company's commercial portfolio through the development of its current pipeline or through strategic collaborations. The Company has no commitments for any additional financing and may not be successful in its efforts to raise additional funds or achieve profitable operations. Any transactions that occur may contain covenants that restrict the ability of management to operate the business or may have rights, preferences or privileges senior to the Company's common stock and may dilute current stockholders of the Company.

The Company filed a shelf registration statement on Form S-3 (File No. 333-238969) on June 5, 2020, which was declared effective by the U.S. Securities and Exchange Commission ("SEC") on June 16, 2020. Under this registration statement, the Company may sell, in one or more transactions, up to $300.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The Company had not sold any securities pursuant to this registration statement as of June 30, 2021.

The Company entered into a Sales Agreement with Cantor Fitzgerald & Co. in August 2017 under which the Company could sell up to $50.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the "ATM Program"). The Company has not sold any securities pursuant to this ATM Program as of June 30, 2021.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company operates in one segment considering the nature of the Company's products and services, class of customers, methods used to distribute its products and the regulatory environment in which the Company operates. The accompanying consolidated financial statements, which include the accounts of Kadmon Holdings, Inc. and its domestic and international subsidiaries have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and pursuant to the rules and regulations of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the Company's opinion, the financial statements include all adjustments (consisting of normal recurring adjustments) and disclosures considered necessary in order to make the financial statements not misleading. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2021.

These unaudited financial statements should be read in conjunction with the audited financial statements included in Item 8 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 4, 2021.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates. The most significant estimates are related to share-based compensation (Note 10) and the accrual of research and development and clinical trial expenses (Note 11).

Critical Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements included in Item 8 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 4, 2021. Since the date of such financial statements, there have been no changes or updates to the Company's significant accounting policies, other than those described below.

Cash, Cash Equivalents and Marketable Debt Securities

The Company considers all highly liquid securities with an original or remaining maturity of three months or less at the time of acquisition to be cash equivalents. The Company determines the appropriate classification of its investments in debt securities at the time of purchase. All of the Company's debt securities are classified as available-for-sale and are reported as short-term or long-term based on maturity dates and whether such assets are available for use in current operations and are reasonably expected to be realized in cash or consumed during the normal cycle of business. Our available-for-sale debt securities generally have contractual maturity dates between six months and two years.

The following tables summarize the Company's cash, cash equivalents and marketable debt securities as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	$ 61,881	$ —	$ —	61,881
Total cash and cash equivalents	61,881	—	—	61,881
Marketable debt securities:				
Corporate debt securities	208,777	11	(175)	208,613
Total marketable debt securities	208,777	11	(175)	208,613
Total cash, cash equivalents and marketable debt securities	**$ 270,658**	**$ 11**	**$ (175)**	**$ 270,494**

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	$ 71,382	$ —	$ —	71,382
Corporate debt securities	3,041			3,041
Total cash and cash equivalents	74,423	—	—	74,423
Marketable debt securities:				
Corporate debt securities	49,463	4	(32)	49,435
Total marketable debt securities	49,463	4	(32)	49,435
Total cash, cash equivalents and marketable debt securities	**$ 123,886**	**$ 4**	**$ (32)**	**$ 123,858**

At June 30, 2021, the Company had invested in 40 available-for-sale marketable debt securities that were in an unrealized loss position for less than one year and no securities in an unrealized loss position for more than one year. The aggregate fair value of debt securities in an unrealized loss position at June 30, 2021 was $173.8 million. The unrealized losses of $0.2 million related to these corporate debt securities were included in accumulated other comprehensive loss as of June 30, 2021. Unrealized losses on corporate debt securities have not been recognized into income because the issuers' bonds are of high credit quality (rated A3/A- or higher), it is likely that management will not be required to sell the securities prior to their anticipated recovery, and the decline in fair value is largely due to market conditions and/or changes in interest rates. The issuers continue to make timely interest payments on the bonds. The fair value is expected to recover as the bonds approach maturity and the Company does not believe any unrealized losses represent other-than-temporary impairments.

Convertible Notes Transaction

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, "*Debt with Conversion and Other Options and Derivatives and Hedging - Contracts in Entity's Own Equity*" ("ASU 2020-06") to address the complexity associated with applying GAAP to certain financial instruments with characteristics of liabilities and equity. This ASU includes amendments to the guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity and simplifies the accounting for convertible instruments by eliminating the cash conversion accounting model for convertible instruments. The Company early adopted ASU 2020-06 effective January 1, 2021, and the standard did not have a significant impact on its consolidated financial statements. By adopting ASU 2020-06, the Company eliminates the separation model for convertible debt and the requirement to separately present in equity an embedded conversion feature in such debt.

In February 2021, the Company issued $240.0 million in aggregate principal of 3.625% convertible senior notes due February 15, 2027 (Note 5). The Company accounts for the convertible notes wholly as debt in accordance with FASB Accounting Standards Codification ("ASC") 470, *Debt*. The Company does not separately account for the liability and equity components of convertible notes transactions that can be settled in cash by allocating the proceeds from issuance between the liability component and the embedded conversion option. The Company recognizes amortization of the debt discount related to issuance costs as interest expense using the effective interest method.

In February 2021, the Company purchased capped call options from financial institutions to minimize the impact of potential dilution of Kadmon common stock upon conversion of the convertible notes. The capped call options meet the definition of a derivative in accordance with FASB ASC 815, *Derivatives and Hedging* ("ASC 815"), however, qualify for derivative scope exception under ASC 815 for instruments indexed to a company's own stock. Accordingly, the premiums for the capped call options were recorded as additional paid-in capital on the Company's consolidated balance sheet as the options are settleable in Kadmon common stock at the election of the Company. See Note 5 for additional information.

Embedded Derivatives

The Company accounts for derivative financial instruments as either equity or liabilities in accordance with ASC 815, based on the characteristics and provisions of each instrument. Embedded derivatives are required to be bifurcated from the host instruments and recorded at fair value if the derivatives are not clearly and closely related to the host instruments on the date of issuance. The Company's convertible notes (Note 5) contain certain features that, in accordance with ASC 815, are not clearly and closely related to the host instrument and represent derivatives that are required to be re-measured at fair value each reporting period. The Company determined that the estimated fair value of the derivatives at issuance and as of June 30, 2021 were not material based on a scenario-based cash flow model that uses unobservable inputs that reflect the Company's own assumptions. Should the Company's assessment of the probabilities around these scenarios change, including due to changes in market conditions, there could be a change to the fair value.

Revenue Recognition

The Company recognizes revenue in accordance with FASB ASC 606, *Revenue from Contracts with Customers*, the core principle of which is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. To achieve this core principle, five basic criteria must be met before revenue can be recognized: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to performance obligations in the contract; and (5) recognize revenue when or as the Company satisfies a performance obligation.

Disaggregation of Revenue

The Company's revenues have primarily been generated through product sales, collaborative research, development and commercialization license agreements, and other service agreements. The following table summarizes revenue from contracts with customers for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product sales	$ 24	$ 299	$ 384	$ 888
License revenue	—	—	—	6,000
Other revenue	173	149	377	295
Total revenue	$ 197	$ 448	$ 761	$ 7,183

Product Sales

These contracts typically include a single promise to deliver a fixed amount of product to the customer with payment due within 30-60 days of shipment. Revenues are recognized when control of the promised goods is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods, which generally occurs upon delivery. The timing of revenue recognition may differ from the timing of invoicing to customers. The Company has not recognized any assets for costs to obtain or fulfill a contract with a customer as of June 30, 2021.

In July 2021, the FDA approved REZUROCK™ (belumosudil) 200 mg QD 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. See Note 14 for additional information.

License Revenue

License revenue in 2020 consists of a milestone payment earned pursuant to a joint venture and license agreement entered into with Meiji Seika Pharma Co., Ltd ("Meiji") to develop belumosudil (KD025) in Japan. The transaction price of $6.0 million was allocated to the single combined performance obligation under the contract and the performance obligation was completed during the first quarter of 2020. There are no performance obligations that have not yet been satisfied and there is no transaction price allocated to future performance obligations as of June 30, 2021.

Other Revenue

The other revenue generated by the Company is primarily related to a sublease agreement with MeiraGTx Holdings plc ("MeiraGTx"). The Company recognizes revenue related to sublease agreements as they are performed.

Related Party Transactions

The Company's related party transactions are disclosed in the audited financial statements included in "Note 2. Summary of Significant Accounting Policies–Related Party Transactions" of the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Since the date of such financial statements, there have been no changes to the Company's related party transactions.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes"*, which removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The Company adopted this standard on January 1, 2021, and the standard did not have a significant impact on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *"Measurement of Credit Losses on Financial Instruments"*, to require financial assets carried at amortized cost to be presented at the net amount expected to be collected based on historical experience, current conditions and forecasts. For smaller reporting companies, the ASU is effective for interim and annual periods beginning after December 15, 2022, with early adoption permitted. Adoption of the ASU is on a modified retrospective basis. The Company does not expect this guidance to have a material impact on its financial statements.

3. Stockholders' Equity

5% Convertible Preferred Stock

The Company had 28,708 shares of 5% convertible preferred stock outstanding at June 30, 2021, which shares convert into shares of the Company's common stock at a 20% discount to the initial public offering price per share of common stock in the Company's initial public offering of $12.00 per share, or $9.60 per share. The stated liquidation preference amount on the 5% convertible preferred stock totaled $36.5 million at June 30, 2021.

Common Stock

The Company's restated certificate of incorporation authorizes the issuance of up to 400,000,000 shares of the Company's common stock, par value $0.001 per share.

4. Net Loss per Share Attributable to Common Stockholders

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Because the Company has reported a net loss for each period presented, diluted net loss per share of common stock is the same as basic net loss per share of common stock for the three and six months ended June 30, 2021 and 2020.

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator – basic and diluted:				
Net loss available to common stockholders - basic and diluted	$ (30,888)	$ (27,670)	$ (59,809)	$ (57,484)
Denominator – basic and diluted:				
Weighted average shares of common stock outstanding used to compute basic and diluted net loss per share	171,967,623	162,416,059	171,829,335	161,101,923
Net loss per share, basic and diluted	**$ (0.18)**	**$ (0.17)**	**$ (0.35)**	**$ (0.36)**

The amounts in the table below were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

	Three and Six Months Ended June 30,	
	2021	2020
Options to purchase common stock	26,253,833	17,486,422
Warrants to purchase common stock	10,582,119	11,917,052
Convertible preferred stock	3,803,490	3,622,371
Convertible notes	34,507,560	—
Total shares of common stock equivalents	**75,147,002**	**33,025,845**

5. Debt

3.625% Convertible Senior Notes Due in 2027

In February 2021, the Company issued $240.0 million in aggregate principal of 3.625% convertible senior notes due February 15, 2027 (the "Notes") through a private placement to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933, as amended. The debt issuance costs of $7.6 million were recorded as a debt discount and are being amortized to interest expense over the contractual term of the Notes.

The Notes, governed by an indenture between the Company and a trustee, are senior, unsecured obligations and do not include financial and operating covenants nor any restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by Kadmon or any of its subsidiaries. Interest on the Notes is payable semi-annually in cash in arrears at a rate of 3.625% per annum on February 15 and August 15 of each year. The Notes will mature February 15, 2027 unless they are redeemed, repurchased or converted prior to such date. Before November 15, 2026, noteholders will have the right to convert their Notes only upon the occurrence of certain events. From and after November 15, 2026, noteholders may convert their Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date.

Upon conversion, the Notes may be settled in shares of Kadmon common stock, cash or a combination thereof, at the Company’s election. The initial conversion rate is 143.7815 shares of common stock per $1,000 in principal amount of Notes, which represents an initial conversion price of approximately $6.96 per share of common stock, or a premium of approximately 30% to the $5.35 per share closing price of the Company’s common stock on February 10, 2021, the date the Company priced the offering. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a “Make-Whole Fundamental Change” (as

defined in the applicable indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Company may redeem all or any portion of the Notes, at its option, on or after February 20, 2024 and on or before the 40th scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, up to, but excluding, the redemption date, but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price then in effect for at least each of 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately before the date the Company provides written notice of redemption; and the trading day immediately before the notice is sent. In addition, calling any Note for redemption will constitute a Make-Whole Fundamental Change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

Holders of Notes may require the Company to repurchase their Notes upon the occurrence of certain events that constitute a fundamental change under the indenture governing the Notes at a fundamental change repurchase price equal to 100% of the principal amount thereof, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The following table summarizes the carrying value of the Notes at June 30, 2021 (in thousands):

	June 30, 2021	December 31, 2020
Gross proceeds	$ 240,000	$ -
Unamortized debt discount	(7,130)	-
Carrying value	$ 232,870	$ -

The following table summarizes the interest expense recognized related to the Notes for the three and six months ended June 30, 2021 (in thousands):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Stated interest	$ 2,175	$ 3,238
Amortized debt discount	317	476
Interest expense	$ 2,492	$ 3,714

Capped Call Transactions

Separately, the Company entered into privately negotiated capped call options with financial institutions. The capped call options cover, subject to customary anti-dilution adjustments, the number of shares of the Company's common stock that initially underlie the Notes. The cap price of the capped call options is $10.70 per share, representing a premium of 100% above the closing price of $5.35 per share of the Company's common stock on February 10, 2021, and is subject to certain adjustments under the terms of the capped call options. The capped call options, which have a final expiration date of February 11, 2027, are generally intended to reduce or offset potential dilution to the Company's common stock upon conversion of the Notes with such reduction and/or offset, subject to a cap based on the cap price. The capped call transactions are separate transactions entered into by the Company, are not part of the terms of the Notes and will not change the holders' rights under the Notes. Holders of the Notes will not have any rights with respect to the capped call options. The Company paid a total of $33.0 million in premiums for the capped call options, which was recorded as additional paid-in capital, using a portion of the gross proceeds from the issuance and sale of the Notes. The capped call options are excluded from diluted earnings per share because the impact would be anti-dilutive.

Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act.

On April 15, 2020, the Company received the proceeds from a loan in the amount of approximately $3.1 million (the "Loan") from PNC Bank, National Association, as lender, pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). Under the CARES Act, loan forgiveness is available for the sum of eligible and documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. On June 10, 2021, the loan was forgiven by the U.S. Small Business Administration ("SBA"). The Company has recorded the forgiven amount of the Loan of approximately $3.1 million as other income for the three and six months ended June 30, 2021.

6. Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy defines three levels and prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of investments and is not a measure of investment credit quality.

Items classified as Level 1 within the valuation hierarchy consist of the Company's cash equivalents held in money market funds and its ownership of MeiraGTx. The Company measures these investments at fair value determined based on Level 1 observable quoted price market inputs.

Items classified as Level 2 within the valuation hierarchy consist of the Company's marketable debt securities, warrant liabilities and convertible notes. The Company estimates the fair values of the marketable debt securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Level 2 inputs used to value the Company's warrant liabilities were determined using prices that can be directly observed. Although the fair value of this obligation is calculated using the observable market price of the Company's common stock, an active market for this financial instrument does not exist. The fair value of the Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices observed in market trading. The market for trading of the Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the Notes was approximately $210.0 million at June 30, 2021.

The following table presents the Company's financial assets and liabilities that have been measured at fair value at June 30, 2021 and the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		Fair Value Measurements Using		
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 54,396	$ 54,396	$ —	$ —
Short-term investments:				
Corporate debt securities	208,613	—	208,613	—
Ownership of MeiraGTx	10,815	10,815	—	—
	$ 273,824	$ 65,211	$ 208,613	$ —
Financial liabilities				
Warrant liabilities	$ 733	$ —	$ 733	$ —

The following table presents the Company's financial assets and liabilities that have been measured at fair value at December 31, 2020 and the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		Fair Value Measurements Using		
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 67,467	$ 67,467	$ —	$ —
Corporate debt securities	3,041	—	3,041	—
Short-term investments:				
Corporate debt securities	49,435	—	49,435	—
Ownership of MeiraGTx	10,564	10,564	—	—
	$ 130,507	$ 78,031	$ 52,476	$ —
Financial liabilities				
Warrant liabilities	$ 1,082	$ —	$ 1,082	$ —

The Company has not recognized any material gross realized gains or losses on sales of available-for-sale marketable debt securities.

Ownership of MeiraGTx

The Company maintained a 1.6% ownership in the ordinary shares of MeiraGTx, a clinical-stage gene therapy company, with a fair value of $10.8 million and $10.6 million, at June 30, 2021 and December 31, 2020, respectively. The Company did not realize any gains in the three and six months ended June 30, 2021, and realized gains of $15.5 million for the three and six months ended June 30, 2020, which represents the sale of 1.1 million ordinary shares of MeiraGTx. The Company has recorded a net unrealized gain on its ownership of MeiraGTx ordinary shares of $0.7 million and $0.3 million for the three and six months ended June 30, 2021, respectively, and net unrealized (loss) of $(15.7) million and $(29.5) million for the three and six months ended June 30, 2020, respectively. The unrealized gains (loss) on equity securities consists of the change in unrealized gain or loss resulting from mark-to-market adjustments on equity securities still held. The Company's ownership of MeiraGTx ordinary shares is valued using Level 1 inputs, which includes quoted prices in active markets for identical assets in accordance with the fair value hierarchy.

Warrant Liabilities

In connection with the 2015 credit agreement, as fees to the lenders thereunder, the Company issued warrants to purchase an aggregate of $6.3 million of the Company's Class A units with an expiration date of August 2022, which were exchanged for 617,651 warrants with a strike price of $10.20 per share to purchase the same number of shares of the Company's common stock upon consummation of the Company's IPO in August 2016 (the "2015 Warrants").

As of June 30, 2021, the exercise price of a portion of the 2015 Warrants to purchase an aggregate of 529,413 shares of the Company's common stock was $3.30 per warrant share and the exercise price of the remaining 2015 Warrants to purchase an aggregate of 88,238 shares of the Company's common stock was $4.50 per warrant share. Since these warrants are exercisable and are redeemable at the option of the holder upon the occurrence of, and during the continuance of, an event of default, the fair value of the 2015 Warrants was recorded as a short-term liability of approximately $0.7 million at June 30, 2021 and approximately $1.1 million at December 31, 2020.

The Company used the Black-Scholes pricing model to value the liability related to the 2015 Warrants at June 30, 2021 with the following assumptions: risk-free interest rate of 0.1%, expected term of 1.2 years, expected volatility of 62.2% and a dividend rate of 0%. The change in fair value of the 2015 Warrants was approximately $(0.1) million and $(0.3) for the three and six months ended June 30, 2021 and approximately $0.3 million and $0.1 for the three and six months ended June 30, 2020, respectively. None of these instruments had been exercised as of June 30, 2021.

The table below represents a roll-forward of warrant liabilities measured using Level 2 inputs from January 1, 2021 to June 30, 2021 (in thousands):

	Significant Other Observable Inputs (Level 2)
Balance at January 1, 2021	$ 1,082
Change in fair value of warrant liabilities	(349)
Balance at June 30, 2021	$ 733

The following table represents a roll-forward of warrants outstanding from January 1, 2021 to June 30, 2021:

	Warrants	Weighted Average Exercise Price
Balance, January 1, 2021	10,582,119	$ 6.30
Exercised	—	—
Balance, June 30, 2021	10,582,119	$ 6.30

7. Inventories

Inventories are stated at the lower of cost or net realizable value (on a first-in, first-out basis) using standard costs. Standard costs include an allocation of overhead rates, which include those costs attributable to managing the supply chain and are evaluated regularly. Variances are expensed as incurred. The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if ever, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development.

The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's product is subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or the Company identifies excess, obsolete or unsalable inventory, its value is written down to net realizable value. Inventories recorded on the Company's consolidated balance sheets are net of a reserve for expirable inventory of $2.0 million and $2.1 million at June 30, 2021 and December 31, 2020, respectively.

Inventories are comprised of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ —	$ —
Finished goods, net	12	102
Total inventories, net	**$ 12**	**$ 102**

8. Fixed Assets

Fixed assets consisted of the following (in thousands):

	Useful Lives (Years)	June 30, 2021	December 31, 2020
Leasehold improvements	4-8	$ 10,397	$ 10,398
Office equipment and furniture	3-15	1,244	1,363
Machinery and laboratory equipment	3-15	3,963	3,835
Software	1-5	4,104	4,136
		19,708	19,732
Less accumulated depreciation and amortization		(18,696)	(18,445)
Fixed assets, net		**$ 1,012**	**$ 1,287**

Depreciation and amortization of fixed assets totaled $0.5 million and $0.8 million for the six months ended June 30, 2021 and 2020, respectively, and $0.2 million and $0.4 million for the three and six months ended June 30, 2021 and 2020, respectively.

9. License Agreements

The Company has entered into several license agreements for products currently under development. The Company's license agreements are disclosed in the audited financial statements included in "Note 11. License Agreements" of its Annual Report on Form 10-K for the year ended December 31, 2020. Since the date of such financial statements, there have been no significant changes to the Company's license agreements.

10. Share-based Compensation

2016 Equity Incentive Plan

A total of 21,785,738 shares of the Company's common stock were authorized and reserved for issuance under the Company's Amended and Restated 2016 Equity Incentive Plan (the "2016 Equity Plan") at December 31, 2020. On January 1, 2021, pursuant to the evergreen provision contained in the 2016 Equity Plan, the number of shares reserved for future grants was increased by 6,861,201 shares, which was four percent (4%) of the outstanding shares of common stock on December 31, 2020. This reserve will increase each subsequent anniversary through January 1, 2025, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Company's board of directors.

The following table summarizes share-based compensation expense under the 2016 Equity Plan for the three and six months ended June 30, 2021 and 2020.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
General and administrative	$ 2,831	$ 1,706	$ 5,561	$ 3,171
Research and development	1,117	914	2,060	1,487
Total stock-based compensation expense	**$ 3,948**	**$ 2,620**	**$ 7,621**	**$ 4,658**

Total unrecognized compensation expense related to unvested options granted under the Company's share-based compensation plan was $31.3 million and $11.9 million at June 30, 2021 and December 31, 2020, respectively. That expense is expected to be recognized over a weighted average period of 2.2 years and 1.9 years as of June 30, 2021 and December 31, 2020, respectively.

The following table summarizes information about stock options outstanding, not including performance stock options, from January 1, 2021 to June 30, 2021:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance, January 1, 2021	16,000,685	$ 5.29	7.11	$ 7,365
Granted	9,821,493	3.96		
Exercised	(361,399)	3.76		434
Forfeited	(496,946)	4.73		
Balance, June 30, 2021	24,963,833	$ 4.80	7.77	$ 5,037
Options vested and exercisable, June 30, 2021	11,348,597	$ 5.76	5.99	$ 4,168

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value calculated as the difference between the fair value of the Company's common stock at June 30, 2021 ($3.87 per share) and December 31, 2020 ($4.15 per share) and the exercise price, multiplied by the related in-the-money options that would have been received by the option holders had they exercised their options at the end of the fiscal year. This amount changes based on the fair value of the Company's common stock.

The fair value of each stock option award, not including performance stock options, was estimated at the date of grant using the Black-Scholes option-pricing model and the assumptions noted in the following table:

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Options granted	9,821,493	4,857,676
Weighted average exercise price	$3.96	$4.35
Weighted average fair value of grants	$2.85	$2.87
Expected volatility	87.20% - 127.92%	75.46% - 81.31%
Risk-free interest rate	0.05% - 1.03%	0.34% - 1.64%
Expected life (years)	0.87 - 6.0	5.5 - 6.0
Expected dividend yield	0%	0%

Performance Options

A total of 1,290,000 performance options ("Performance Options") with an exercise price of $4.06 were outstanding at June 30, 2021 with no intrinsic value and at December 31, 2020 with an intrinsic value of $0.3 million. The weighted average remaining contractual life of outstanding Performance Options at June 30, 2021 was 5.2 years. Compensation expense for Performance Options was recognized on a straight-line basis over the awards' requisite service period of three years. At both June 30, 2021 and December 31, 2020, 962,502 Performance Options had vested and no Performance Options had been exercised.

Stock Appreciation Rights

A total of 835,000 stock appreciation rights ("SARs") with an exercise price of $3.64 were outstanding at June 30, 2021 and December 31, 2020 with an intrinsic value of $0.2 million and $0.5 million, respectively. The weighted average remaining contractual life of outstanding SARs at June 30, 2021 was 5.1 years. Compensation expense for SARs was recognized on a straight-line basis over three years. At both June 30, 2021 and December 31, 2020, 835,000 SARs had vested and no SARs had been exercised.

2014 Long-term Incentive Plan (the "LTIP")

A total of 9,750 units have been granted under the LTIP as of both June 30, 2021 and December 31, 2020. The LTIP is payable upon the fair market value of the Company's common stock exceeding 333% of the $6.00 grant price (or $20.00) per share prior to December 7, 2024. The holders of the LTIP awards have no right to demand a particular form of payment, and the Company reserves the right to make payment in the form of cash or common stock. No LTIP awards were exercisable or had been exercised at June 30, 2021.

2016 Employee Stock Purchase Plan

A total of 2,551,180 shares of the Company's common stock were reserved for issuance under the Amended and Restated 2016 Employee Stock Purchase Plan (the "2016 ESPP") at December 31, 2020. The Company's board of directors elected not to increase the shares reserved for issuance under the 2016 ESPP on January 1, 2021. The Company issued 94,420 and 98,840 shares under the 2016 ESPP during the six months ended June 30, 2021 and 2020, respectively. No meaningful compensation expense was recognized for the ESPP during the three and six months ended June 30, 2021 or 2020.

11. Accrued Expenses

Short-term accrued expenses at June 30, 2021 and December 31, 2020 include the following (in thousands):

	June 30, 2021	December 31, 2020
Compensation and benefits	$ 3,457	$ 5,585
Research and development	5,863	4,183
Interest	3,238	20
Other	1,986	1,746
Total accrued expenses	$ 14,544	$ 11,534

Compensation and benefits

Compensation and benefits primarily represents earned and unpaid employee wages and bonuses.

Research and development

The Company has contracts with third parties for the development of the Company's product candidates. The timing of the expenses varies depending upon the timing of initiation of clinical trials and enrollment of patients in clinical trials.

Interest

Interest represents accrued and unpaid interest on the Company's outstanding indebtedness (Note 5).

12. Commitments and Contingencies

The Company's commitments are disclosed in the audited financial statements included in "Note 15. Commitments and Contingencies" of the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Since the date of such financial statements, there have been no material changes to the Company's commitments or contingencies, including leases, other than the legal proceedings described below.

Contingent License Agreement Milestones

The Company has entered into several license agreements for products currently under development (Note 9). The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent milestone payments aggregate to $229.1 million at June 30, 2021. Any payments made prior to FDA approval will be expensed as research and development. Any payments made after FDA approval will be capitalized.

Under the terms of certain licensing agreements, the Company may be obligated to pay commercial milestones contingent upon the realization of sales revenues and sublicense revenues. Due to the long-range nature of such commercial milestones, they are neither probable at this time nor predictable, and consequently are not included in the additional contingent milestone payment amount.

Legal Proceedings

The Company is subject to various legal proceedings that arise from time to time in the ordinary course of its business. Although the Company believes that the various proceedings brought against it are without merit, and that it has adequate product liability and other insurance to cover any claims, litigation is subject to many factors which are difficult to predict and there can be no assurance that the Company will not incur material costs in the resolution of legal matters. Should the Company determine that any future obligations will exist, the Company will record expense equal to the amount which is deemed probable and estimable.

Rafik Tadros v. Kadmon Holdings, Inc., Harlan W. Waksal, and Steven Meehan

On April 2, 2021, Rafik Tadros, a purported stockholder of the Company, and the Lead Plaintiff filed the above styled putative class action complaint against the Company, its Chief Executive Officer and its Chief Financial Officer ("Defendants"), alleging that from October 1, 2020 through March 10, 2021, Defendants made materially false and misleading statements to the Company's stockholders regarding the Belumosudil New Drug Application and the FDA's review process related thereto. The Defendants denied all allegations and believed they were without merit. On July 22, 2021, the Lead Plaintiff filed a notice of voluntary dismissal and the case was terminated by Judge Pamela K. Chen in accordance therewith.

GoldenTree Master Fund, Ltd. v. Kadmon Holdings, Inc.

On April 21, 2021, GoldenTree Master Fund, Ltd ("GoldenTree") filed suit in the Supreme Court of New York bringing claims for breach of contract, unjust enrichment, and fraudulent inducement. The claims relate to email correspondence pursuant to which the Company allegedly committed to work with GoldenTree in good faith to try and achieve either a third-party sale or exchange into registered common shares GoldenTree's preferred shares of the Company. The Company has filed a motion to dismiss and a reply to the Plaintiff's response to such motion to dismiss, and is awaiting the Court's hearing and decision related thereto. The Company continues to deny the allegations and believes the claims are without merit.

13. Income Taxes

The Company files a consolidated tax return for Kadmon Holdings, Inc. and its domestic subsidiaries and the required information returns for its international subsidiaries, all of which are wholly owned. Where permitted, the Company files combined state returns, but in some instances separate company returns for certain subsidiaries on a stand-alone basis are required.

There was no change in deferred tax liability and no income tax expense recorded for the three and six months ended June 30, 2021 and 2020. Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss ("NOL") carryforwards and other balance sheet basis differences. In accordance with ASC 740, *Income Taxes*, the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets at June 30, 2021 and December 31, 2020.

At December 31, 2020, the Company had unused federal and state NOL carryforwards of $408.4 million and $349.6 million, respectively, that may be applied against future taxable income. The Company has fully reserved the deferred tax asset related to these NOL carryforwards as reflected in its consolidated financial statements. Approximately $291.1 million of the federal NOL carryforwards expire at various dates through December 31, 2037, and approximately $117.3 million of federal net operating loss carryforwards will not expire. Approximately all of the $349.6 million state NOL carryforwards expire at various dates through December 31, 2040.

14. Subsequent Events

REZUROCK FDA Approval

In July 2021, the FDA approved REZUROCK™ (belumosudil) 200 mg QD 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. The Company expects REZUROCK to be its principal source of product sales in the future. REZUROCK is expected to be available in the United States by late August 2021. For REZUROCK, the Company will classify payments to its customer for certain services provided by its customer as reductions to revenue.

The Company will sell REZUROCK directly to patients through a limited distribution network of specialty pharmacy and specialty distributors in the United States. Net revenue from sales of REZUROCK will be recorded at net selling price (transaction price), which includes estimates of variable consideration for which reserves are established for (i) estimated commercial and government rebates, such as Medicaid and Medicare Part D reimbursements, and estimated managed care rebates, (ii) estimated chargebacks, (iii) estimated costs of co-payment assistance programs and (iv) product returns.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the "Company," "Kadmon," "we," "us" and "our" refer to Kadmon Holdings, Inc. and its consolidated subsidiaries. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Quarterly Report on Form 10-Q and those in included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2020. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" and "Forward-Looking Statements" sections of this Quarterly Report on Form 10-Q and our most recent Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address significant unmet medical needs. Our clinical pipeline includes developmental treatments for immune and fibrotic diseases as well as immuno-oncology therapies. Our operations to date have been focused on developing first-in-class innovative therapies for indications with significant unmet medical needs while leveraging our commercial infrastructure. We believe that we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. In addition to these discovery and development efforts, our business strategy includes the efficient commercialization of these drugs in the U.S. and certain other regions upon regulatory approval. By focusing on rare disease markets, we believe that we can more effectively control the costs of, and our strategic allocation of financial resources toward, post-approval commercialization.

Our revenues are difficult to predict and depend on several factors. For example, our revenues depend, in part, on regulatory approval decisions for our product and product candidates, the effectiveness of our and our collaborative partners' commercialization efforts, market acceptance of our products, particularly REZUROCK™ (belumosudil), the resources dedicated to our products and product candidates by us and our collaborative partners, and our ability to enter into or modify licensing agreements for our product candidates. We have never been profitable and had an accumulated deficit of $503.9 million at June 30, 2021.

Our operating expenses are also difficult to predict and depend on several factors, including commercialization expenses, research and development expenses, drug manufacturing, and clinical research activities, the ongoing requirements of our development programs and the availability of capital. As our commercialization activities for REZUROCK and research and development programs continue to advance, we expect our operating costs will increase. Management may be able to control the timing and level of research and development and selling, general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period-to-period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. The Company has sustained operating losses for the majority of its corporate history and the Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Recent Corporate Highlights

COVID-19 Update

The ongoing COVID-19 pandemic has severely impacted global economic activity and caused significant volatility in financial markets. While our financial condition, results of operations, cybersecurity and liquidity have not been materially impacted by the direct effects of the pandemic, the COVID-19 pandemic continues to evolve. We are continuing to monitor developments with respect to the COVID-19 pandemic and to make adjustments as needed to assist in protecting the safety of our employees and communities while continuing our business activities. To date, implementation of these measures has not required material expenditures or significantly impacted our ability to operate our business or our internal control over financial reporting and disclosure controls and procedures. We are continuing to monitor the potential impacts of COVID-19 on our operations and those of our partners, suppliers, customers, and regulators, including commercial and clinical drug supply chain continuity and commercial launch of REZUROCK.

Notwithstanding the foregoing, we cannot precisely predict the impact that the COVID-19 pandemic will have in the future due to numerous uncertainties, including the severity of the disease and its variants, the duration of the pandemic, actions that may be taken by governmental authorities, the impact to the business of potential variations or disruptions in our supply chain, and other factors identified in Part I, Item 1A. “Risk Factors” included in our Annual Report on Form 10-K for the year ended December 31, 2020. We will continue to closely monitor and evaluate the nature and extent of the impact of the COVID-19 pandemic to our business, consolidated results of operations, and financial condition.

REZUROCK™ (belumosudil)

REZUROCK is an oral tablet developed by Kadmon for the treatment of cGVHD. REZUROCK was approved by the FDA on July 16, 2021 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. We expect REZUROCK to be available in the United States by late August 2021.

We expect to begin generating revenue from sales of REZUROCK in the third quarter of 2021. Revenue from sales of REZUROCK in future periods is subject to uncertainties and will depend on several factors, including the success of our and our partners’ commercialization efforts in the U.S., the number of new patients switching to REZUROCK, patient retention and demand, the number of physicians prescribing REZUROCK, the rate of monthly prescriptions, reimbursement from third-party payors, the conversion of patients from our clinical trials to commercial customers, and market trends. We will monitor and analyze this data during the initial launch period.

Belumosudil for the treatment of systemic sclerosis

We are also developing belumosudil for the treatment of systemic sclerosis (“SSc”). A double-blind, placebo-controlled, 60-patient Phase 2 clinical trial of belumosudil in diffuse cutaneous SSc (“dcSSc”) (KD025-209) is ongoing, and an open-label Phase 2 clinical trial of belumosudil in dcSSc designed to quickly present the potential of belumosudil in dcSSc while the placebo-controlled trial is ongoing. We plan to present initial data from the open-label study by year-end 2021. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of SSc.

KD033

We have a biologics research platform focused on the development of immuno-oncology therapeutics, specifically, IL-15-containing fusion proteins for the treatment of cancer. KD033 is an anti-PD-L1/IL-15 fusion protein and is the most advanced product candidate from our IL-15 platform. A Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors (KD033-101) is ongoing. In May 2021, we presented initial safety data demonstrating that KD033 was well tolerated in all patients through initial dose cohorts, allowing for continuation of dose escalation. We plan to share additional clinical data from this trial in the fourth quarter of 2021.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reporting amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change, and regularly discuss financial events, policies, and issues with members of our audit committee. In particular, we routinely evaluate our estimates and policies regarding revenue recognition, share-based compensation and the accrual of research and development and clinical trial expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

See our significant accounting policies disclosed in “Note 2. Summary of Significant Accounting Policies” in our audited financial statements for the year ended December 31, 2020 included in our Annual Report on Form 10-K for a description of accounting policies that we believe are the most critical to aid you in fully understanding and evaluating our reported financial results and that affect the more significant judgments and estimates that we use in the preparation of our financial statements. Since the date of such financial statements, there have been no changes to our significant accounting policies other than those described in Note 2 of the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See Note 2 of the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of recently issued and adopted accounting pronouncements.

Results of Operations

Three and six months ended June 30, 2021 and 2020

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited) (in thousands)			
Revenues				
Net sales	$ 24	$ 299	$ 384	$ 888
Other revenue	173	149	377	6,295
Total revenue	197	448	761	7,183
Cost of sales and inventory write-down	11	784	107	1,396
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)

Revenues

The decrease in total revenue for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 was primarily attributable to a $6.0 million milestone payment earned in the first quarter of 2020 pursuant to a joint venture and license agreement entered into with Meiji Seika Pharma Co., Ltd to develop belumosudil in Japan.

Research and development expenses

The increase in research and development expenses for the three and six months ended June 30, 2021 as compared to the three and six months ended June 30, 2020 was primarily related to an increase in direct external costs of developing our preclinical product candidates from our immuno-oncology platform.

Selling, general and administrative expenses

The increase in selling, general and administrative expenses for the three and six months ended June 30, 2021 as compared to the three and six months ended June 30, 2020 was primarily attributable to increased expenses related to the preparation for the launch of REZUROCK, as well as employee stock compensation.

Total other income (expense)

The following table provides components of other income (expense):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited) (in thousands)			
Interest income	$ 1,120	$ 128	$ 1,720	$ 594
Interest expense	(2,497)	(5)	(3,726)	(5)
Unrealized gain (loss) on equity securities	747	(15,702)	251	(29,505)
Realized gain on equity securities	—	15,510	—	15,510
Gain on extinguishment of obligation	3,091	—	3,091	—
Other expense	(811)	(163)	(662)	(6)
Total other income (expense)	**$ 1,650**	**$ (232)**	**$ 674**	**$ (13,412)**

The increase in other income for the three and six months ended June 30, 2021 as compared to the three and six months ended June 30, 2020 was primarily attributable to the fluctuations in our ownership of MeiraGTx ordinary shares and PPP loan forgiveness in June 2021 of approximately $3.1 million, offset by the increase in interest expense related to our convertible notes issued in February 2021.

Deemed dividend on convertible preferred stock

We have 28,708 shares of 5% convertible preferred stock outstanding at June 30, 2021, which accrue dividends at a rate of 5% and convert into shares of our common stock at a 20% discount to the initial public offering price per share of common stock in our IPO of $12.00 per share, or $9.60 per share. The stated liquidation preference amount on the 5% convertible preferred stock totaled $36.5 million at June 30, 2021.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception through June 30, 2021, we have raised net proceeds from the issuance of equity and debt. We maintained cash, cash equivalents and marketable debt securities of $270.5 million at June 30, 2021. We expect that our cash, cash equivalents and marketable debt securities as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements into 2023, based on our current business plan.

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each period set forth below:

	Six Months Ended June 30,	
	2021	2020
	(unaudited) (in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (52,568)	$ (37,514)
Investing activities	(161,039)	15,350
Financing activities	201,065	52,371
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (12,542)	$ 30,207

Operating Activities

The net cash used in operating activities was $52.6 million for the six months ended June 30, 2021, and consisted primarily of a net loss of $(58.7) million adjusted for $7.9 million in net non-cash items, primarily including share-based compensation expense of $7.6 million and depreciation and amortization of fixed assets and noncash operating lease cost of $2.4 million, as well as a net decrease in operating assets and liabilities of $1.6 million. Once adjusted for the non-cash items above, the cash used in operating activities for the six months ended June 30, 2021 was primarily driven by selling, general and administrative expenses of $18.4 million and research and development expense of $31.8 million related to the advancement of our clinical product candidates.

The net cash used in operating activities was $37.5 million for the six months ended June 30, 2020, and consisted primarily of a net loss of $(56.4) million adjusted for $22.3 million in net non-cash items, including unrealized loss on equity securities of $14.0 million, offset by the depreciation and amortization of fixed assets and noncash operating lease cost of $2.6 million, write-down of inventory of $0.9 million, change in fair value of warrant liabilities of $0.1 million and share-based compensation expense of $4.7 million, as well as a net decrease in operating assets and liabilities of $3.2 million. Once adjusted for the non-cash items above, the cash used in operating activities for the six months ended June 30, 2020 was primarily driven by selling, general and administrative expenses of $13.6 million and research and development expense of $27.9 million related to the advancement of our clinical product candidates.

Investing Activities

Net cash used in investing activities was $161.0 million for the six months ended June 30, 2021, consisting primarily of net purchases of investment debt securities of $160.8 million.

Net cash provided by investing activities was $15.4 million for the six months ended June 30, 2020, consisting of proceeds from the sale of a portion of our investment in MeiraGTx of $15.5 million.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was $201.1 million, consisting primarily of net proceeds from the issuance of our convertible notes of $232.4 million in Februrary 2021, offset by the payments for capped call transactions in connection with the convertible notes of $33.0 million. For more information, please refer to Note 5 of the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Net cash provided by financing activities for the six months ended June 30, 2020 was $52.4 million, consisting primarily of net proceeds from the issuance of common stock in our ATM Offering of $48.4 million.

Future Funding Requirements

Our operations have principally been funded through the issuance of equity and debt securities. As our commercialization activities and our planned research and development programs continue to advance, we expect our costs will increase. Furthermore, given the uncertain economic conditions caused by the COVID-19 pandemic, we will continue to monitor the nature and extent of the impact of the COVID-19 pandemic on our liquidity and capital resources. As a result, our management will retain broad discretion over the allocation of our existing cash, cash equivalents and marketable debt securities.

The expected use of our cash, cash equivalents and marketable debt securities at June 30, 2021 represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Additional funding, whether through additional sales of equity or debt securities, collaborative or other arrangements with corporate partners or from other sources, may not be available when needed or on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate certain of our research and development programs.

Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates and commercialization of REZUROCK. More specifically, our working capital requirements will be dependent on:

- the timing, magnitude and scope of commercial spending and our development programs;
- regulatory approval of our product candidates;
- the costs of obtaining patent protection for our product candidates;
- the timing and terms of business development activities;
- the rate of technological advances relevant to our operations;
- the efficiency of manufacturing processes developed on our behalf by third parties; and
- the level of required administrative support for our daily operations.

Contractual Obligations and Commitments

There have been no material changes in our contractual obligations and commitments during the six months ended June 30, 2021 from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 4, 2021.

Off-balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules. We may be obligated in future periods to make contingent payments, which would become due and payable only upon the achievement of certain research and development, regulatory and approval milestones (see Note 12 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a “smaller reporting company”, we are not required to provide the information required by this item.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), to allow timely decisions regarding required disclosure.

As of June 30, 2021, our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our CEO and CFO have concluded based upon the evaluation described above that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended), occurred during the fiscal quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Please refer to Note 12 of the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a discussion related to our legal proceedings.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our most recent Annual Report on Form 10-K for the year ended December 31, 2020, which could materially and adversely affect our business, financial condition or future results. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks actually occur, our business, financial condition or results of operations could be materially and adversely affected. There are no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1	Amended and Restated Kadmon Holdings, Inc. 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on May 12, 2021).
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101)

*Filed herewith.

**Furnished herewith. The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Kadmon Holdings, Inc.

Date: August 5, 2021 By: /s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2021 By: /s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: August 5, 2021 By: /s/ Kyle Carver
Kyle Carver
Senior Vice President, Chief Accounting Officer, Controller
(Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULES 13A-14 AND 15D-14(A) PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Harlan W. Waksal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kadmon Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended, Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2021

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULES 13A-14 AND 15D-14(A) PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Steven Meehan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kadmon Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended, Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2021

/s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kadmon Holdings, Inc. (the "Company") for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Harlan W. Waksal, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 5, 2021

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kadmon Holdings, Inc. (the "Company") for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven Meehan, Executive Vice President, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 5, 2021

/s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer