

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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**

(State or other jurisdiction of incorporation or organization)

**450 East 29th Street, New York, NY**  
(Address of principal executive offices)

**27-3576929**  
(I.R.S. Employer Identification No.)

**10016**  
(Zip Code)

**(212) 308-6000**

(Registrant's telephone number, including area code)

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  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  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  Smaller reporting company  Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	KDMN	The New York Stock Exchange

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

The number of shares of the registrant's common stock outstanding as of November 4, 2019 was 129,690,886.

[Table of Contents](#)

Kadmon Holdings, Inc.

Form 10-Q

Table of Contents

	<b>Page</b>
<b><u>PART I – Financial Information</u></b>	
<b><u>Item 1</u></b>	
Consolidated financial statements:	5
Consolidated balance sheets as of September 30, 2019 (unaudited) and December 31, 2018	5
Consolidated statements of operations for the three and nine months ended September 30, 2019 and 2018 (unaudited)	6
Consolidated statements of stockholders' equity for the nine months ended September 30, 2019 and the year ended December 31, 2018(unaudited)	7
Consolidated statements of cash flows for the nine months ended September 30, 2019 and 2018 (unaudited)	8
Notes to consolidated financial statements (unaudited)	9
<b><u>Item 2</u></b>	
Management's Discussion and Analysis of Financial Condition and Results of Operations	28
<b><u>Item 3</u></b>	
Quantitative and Qualitative Disclosures About Market Risk	33
<b><u>Item 4</u></b>	
Controls and Procedures	33
<b><u>PART II – Other Information</u></b>	
<b><u>Item 1</u></b>	
Legal Proceedings	34
<b><u>Item 1A</u></b>	
Risk Factors	34
<b><u>Item 2</u></b>	
Unregistered Sales of Equity Securities and Use of Proceeds	34
<b><u>Item 3</u></b>	
Defaults Upon Senior Securities	34
<b><u>Item 4</u></b>	
Mine Safety Disclosures	34
<b><u>Item 5</u></b>	
Other Information	34
<b><u>Item 6</u></b>	
Exhibits	35
<b><u>Signatures</u></b>	<b>37</b>

## 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 capital expenditures and debt service obligations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, the following:

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our reliance on the success of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- our ability to expand our sales and marketing capabilities;
- the commercialization, pricing and reimbursement of our product candidates, if approved;
- 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 candidates and technology;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- 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;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding;
- the rate and degree of market acceptance, if any, of our product candidates, if approved;
- 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;
- our ability to achieve cost savings and benefits from our efforts to streamline our operations and to not harm our business with such efforts;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements 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 and cash equivalents and other sources of liquidity;
- our ability to repay, amend or refinance our credit agreement with Perceptive Credit Opportunities Fund, L.P. as amended, due July 1, 2020 (the “2015 Credit Agreement”);
- the future trading price of shares of our common stock and impact of securities analysts’ reports on these prices;
- the future trading price of our investment securities and our potential inability to sell those securities;
- our ability to apply unused federal and state net operating loss carryforwards against future taxable income; and
- other risks and uncertainties, including those listed in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K.

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.

## PART I. FINANCIAL INFORMATION

**Kadmon Holdings, Inc.**  
**Consolidated balance sheets**  
**(in thousands, except share and per share amounts)**

	September 30, 2019 (unaudited)	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 66,132	\$ 94,740
Accounts receivable, net	687	1,690
Inventories, net	214	925
Investment, equity securities	56,379	—
Prepaid expenses and other current assets	1,048	1,581
Total current assets	124,460	98,936
Fixed assets, net	2,728	3,654
Right of use lease asset	20,510	—
Goodwill	3,580	3,580
Restricted cash	2,116	2,116
Investment, equity securities	—	34,075
Investment, at cost	2,300	2,300
Other noncurrent assets	187	—
Total assets	\$ 155,881	\$ 144,661
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 8,484	\$ 9,986
Accrued expenses	13,578	13,508
Lease liability - current	3,905	—
Fair market value of financial instruments	594	524
Secured term debt – current	27,763	—
Total current liabilities	54,324	24,018
Lease liability - noncurrent	20,774	—
Deferred rent	—	4,290
Deferred tax liability	415	415
Other long term liabilities	244	47
Secured term debt – net of current portion and discount	—	27,480
Total liabilities	75,757	56,250
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; 28,708 and 30,000 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	41,915	42,231
Common stock, \$0.001 par value; 400,000,000 and 200,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; 129,634,540 and 113,130,817 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	130	113
Additional paid-in capital	358,905	315,710
Accumulated deficit	(320,826)	(269,643)
Total stockholders' equity	80,124	88,411
Total liabilities and stockholders' equity	\$ 155,881	\$ 144,661

See accompanying notes to consolidated financial statements (unaudited)

[Table of Contents](#)

**Kadmon Holdings, Inc.**  
**Consolidated statements of operations (unaudited)**  
**(in thousands, except share and per share amounts)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Revenues:				
Net sales	\$ 50	\$ 198	\$ 164	\$ 633
Other revenue	176	174	529	531
Total revenue	226	372	693	1,164
Cost of sales	73	59	149	361
Write-down of inventory	—	20	932	265
Gross profit	153	293	(388)	538
Operating expenses:				
Research and development	13,227	11,918	43,326	31,876
Selling, general and administrative	10,174	9,668	27,101	26,730
Total operating expenses	23,401	21,586	70,427	58,606
Loss from operations	(23,248)	(21,293)	(70,815)	(58,068)
Other (expense) income:				
Interest income	418	534	1,622	742
Interest expense	(931)	(877)	(2,799)	(3,680)
Change in fair value of financial instruments	(126)	198	(70)	802
Loss on equity method investment	—	—	—	(1,242)
Unrealized (loss) gain on equity securities	(38,634)	7,564	22,304	48,072
Other income	126	75	115	77
Total other (expense) income	(39,147)	7,494	21,172	44,771
Loss before income tax benefit	(62,395)	(13,799)	(49,643)	(13,297)
Income tax benefit	—	—	—	562
Net loss	\$ (62,395)	\$ (13,799)	\$ (49,643)	\$ (12,735)
Deemed dividend on convertible preferred stock	517	515	1,540	1,496
Net loss attributable to common stockholders	\$ (62,912)	\$ (14,314)	\$ (51,183)	\$ (14,231)
Basic and diluted net loss per share of common stock	\$ (0.49)	\$ (0.13)	\$ (0.40)	\$ (0.15)
Weighted average basic and diluted shares of common stock outstanding	128,225,469	113,101,776	128,360,618	92,378,205

See accompanying notes to consolidated financial statements (unaudited)

[Table of Contents](#)

**Kadmon Holdings, Inc.**  
**Consolidated statements of stockholders' equity (unaudited)**  
(in thousands, except share amounts)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	30,000	\$ 40,220	78,643,954	\$ 79	\$ 198,856	\$ (237,397)	\$ 1,758
Share-based compensation expense	—	—	—	—	2,572	—	2,572
Common stock issued for warrant exercises	—	—	8,195	—	26	—	26
Cumulative effect of change in accounting principle - ASC 606 adoption	—	—	—	—	—	24,017	24,017
Beneficial conversion feature on convertible preferred stock	—	98	—	—	—	(98)	—
Accretion of dividends on convertible preferred stock	—	392	—	—	—	(392)	—
Net loss	—	—	—	—	—	(20,441)	(20,441)
Balance, March 31, 2018	30,000	\$ 40,710	78,652,149	\$ 79	\$ 201,454	\$ (234,311)	\$ 7,932
Share-based compensation expense	—	—	—	—	3,023	—	3,023
Common stock issued in public offering, net	—	—	34,303,030	34	105,727	—	105,761
Common stock issued for warrant exercises	—	—	123,639	—	562	—	562
Common stock issued under ESPP plan	—	—	22,958	—	65	—	65
Beneficial conversion feature on convertible preferred stock	—	98	—	—	—	(98)	—
Accretion of dividends on convertible preferred stock	—	393	—	—	—	(393)	—
Net income	—	—	—	—	—	21,505	21,505
Balance, June 30, 2018	30,000	\$ 41,201	113,101,776	\$ 113	\$ 310,831	\$ (213,297)	\$ 138,848
Share-based compensation expense	—	—	—	—	2,833	—	2,833
Beneficial conversion feature on convertible preferred stock	—	103	—	—	—	(103)	—
Accretion of dividends on convertible preferred stock	—	412	—	—	—	(412)	—
Net loss	—	—	—	—	—	(13,799)	(13,799)
Balance, September 30, 2018	30,000	\$ 41,716	113,101,776	\$ 113	\$ 313,664	\$ (227,611)	\$ 127,882
Share-based compensation expense	—	—	—	—	1,963	—	1,963
Common stock issued under ESPP plan	—	—	29,041	—	83	—	83
Beneficial conversion feature on convertible preferred stock	—	103	—	—	—	(103)	—
Accretion of dividends on convertible preferred stock	—	412	—	—	—	(412)	—
Net loss	—	—	—	—	—	(41,517)	(41,517)
Balance, December 31, 2018	30,000	\$ 42,231	113,130,817	\$ 113	\$ 315,710	\$ (269,643)	\$ 88,411
Share-based compensation expense	—	—	—	—	2,156	—	2,156
Common stock issued in public offering, net	—	—	13,778,705	14	29,035	—	29,049
Beneficial conversion feature on convertible preferred stock	—	103	—	—	—	(103)	—
Accretion of dividends on convertible preferred stock	—	412	—	—	—	(412)	—
Net income	—	—	—	—	—	3,592	3,592
Balance, March 31, 2019	30,000	\$ 42,746	126,909,522	\$ 127	\$ 346,901	\$ (266,566)	\$ 123,208
Share-based compensation expense	—	—	—	—	1,969	—	1,969
Common stock issued in public offering, net	—	—	2,538,100	3	6,644	—	6,647
Common stock issued under ESPP plan	—	—	32,273	—	73	—	73
Beneficial conversion feature on convertible preferred stock	—	102	—	—	—	(102)	—
Accretion of dividends on convertible preferred stock	—	406	—	—	—	(406)	—
Common stock issued upon conversion of convertible preferred stock	(1,292)	(1,856)	154,645	—	1,856	—	—
Net income	—	—	—	—	—	9,160	9,160
Balance, June 30, 2019	28,708	\$ 41,398	129,634,540	\$ 130	\$ 357,443	\$ (257,914)	\$ 141,057
Share-based compensation expense	—	—	—	—	1,462	—	1,462
Beneficial conversion feature on convertible preferred stock	—	103	—	—	—	(103)	—
Accretion of dividends on convertible preferred stock	—	414	—	—	—	(414)	—
Net loss	—	—	—	—	—	(62,395)	(62,395)
Balance, September 30, 2019	28,708	\$ 41,915	129,634,540	\$ 130	\$ 358,905	\$ (320,826)	\$ 80,124

See accompanying notes to consolidated financial statements (unaudited)

[Table of Contents](#)

**Kadmon Holdings, Inc.**  
**Consolidated statements of cash flows (unaudited)**  
**(in thousands)**

	Nine Months Ended September 30,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (49,643)	\$ (12,735)
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization of fixed assets	1,356	1,105
Amortization of right of use lease asset	2,495	—
Write-down of inventory	932	265
Amortization of deferred financing costs	—	228
Amortization of debt discount	283	1,077
Amortization of debt premium	—	(345)
Share-based compensation	5,587	8,428
Change in fair value of financial instruments	70	(802)
Loss on equity method investment	—	1,242
Unrealized gain on equity securities	(22,304)	(48,072)
Deferred tax liability	—	(562)
Changes in operating assets and liabilities:		
Accounts receivable, net	1,003	207
Inventories, net	(221)	(1,127)
Prepaid expenses and other assets	346	(1,109)
Accounts payable	(1,402)	(1,072)
Lease liability	(2,763)	—
Accrued expenses, other liabilities and deferred rent	314	686
Net cash used in operating activities	<u>(63,947)</u>	<u>(52,586)</u>
<b>Cash flows from investing activities:</b>		
Purchases of fixed assets	(430)	(811)
Net cash used in investing activities	<u>(430)</u>	<u>(811)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net	35,696	105,761
Payments of financing costs	—	(596)
Principal payments on secured term debt	—	(6,574)
Proceeds from issuance of ESPP shares	73	65
Proceeds from exercise of warrants	—	575
Net cash provided by financing activities	<u>35,769</u>	<u>99,231</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(28,608)</u>	<u>45,834</u>
Cash, cash equivalents and restricted cash, beginning of period	96,856	69,633
Cash, cash equivalents and restricted cash, end of period	<u>\$ 68,248</u>	<u>\$ 115,467</u>
<b>Components of cash, cash equivalents and restricted cash</b>		
Cash and cash equivalents	66,132	113,351
Restricted cash	2,116	2,116
Total cash, cash equivalents and restricted cash	<u>68,248</u>	<u>115,467</u>
<b>Supplemental cash flow disclosures:</b>		
Cash paid for interest	\$ 2,514	\$ 2,750
<b>Non-cash investing and financing activities:</b>		
Beneficial conversion feature on convertible preferred stock	308	299
Accretion of dividends on convertible preferred stock	1,232	1,197
Operating lease liabilities arising from obtaining right-of-use assets	212	—
Cumulative effect of change in accounting principle - ASC 842 adoption	27,083	—
Cumulative effect of change in accounting principle - ASC 606 adoption	—	24,017
Common stock issued upon conversion of convertible preferred stock	1,856	—

See accompanying notes to consolidated financial statements (unaudited)

**Kadmon Holdings, Inc.**

**Notes to consolidated financial statements (unaudited)**

**1. Organization**

*Nature of Business*

Kadmon Holdings, Inc. (together with its subsidiaries, “Kadmon” or the “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 inflammatory and fibrotic diseases as well as immuno-oncology. The Company leverages its multi-disciplinary research and clinical 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. The Company believes that it has the ability to develop these candidates while maintaining flexibility for commercial and licensing arrangements. The Company expects to continue to progress its clinical candidates and have further clinical trial events in the remainder of 2019 and in 2020.

*Liquidity*

The Company maintained cash and cash equivalents of \$66.1 million at September 30, 2019. The Company had an accumulated deficit of \$320.8 million and working capital of \$70.1 million at September 30, 2019. Subsequently, in October 2019, the Company entered into a transaction pursuant to which it sold approximately 1.4 million ordinary shares of MeiraGTx Holdings plc (“MeiraGTx”) for gross proceeds of \$22.0 million. Pursuant to the 2015 Credit Agreement, half of the proceeds received from the sale, or \$11.0 million, were used to pay down part of the outstanding amounts owed under the 2015 Credit Agreement. After this repayment, approximately \$17.0 million remained outstanding under the 2015 Credit Agreement (Note 5). The remaining \$11.0 million in gross proceeds were added to the Company’s cash balances in October 2019. The Company expects that its cash and cash equivalents will enable it to advance its Phase 2 clinical studies of KD025 and advance certain of its other pipeline product candidates and provide for other working capital purposes.

Management’s plans include continuing to finance operations through the issuance 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. 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. 333-233766) on September 13, 2019, which was declared effective by the Securities Exchange Commission (“SEC”) on September 24, 2019. Under this registration statement, the Company may sell, in one or more transactions, up to \$200.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units, an amount which includes \$50.0 million of shares of its common stock that may be issued in one or more “at-the-market” placements at prevailing market prices under the Company’s Controlled Equity Offering<sup>SM</sup> Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”) The Company had not sold any securities pursuant to this registration statement as of September 30, 2019.

In April 2019, the Company sold 2,538,100 shares of common stock at a price of \$2.70 per share and received total gross proceeds of \$6.9 million (\$6.7 million net of \$0.2 million of commissions payable by the Company) and in January 2019, the Company sold 13,778,705 shares of common stock at a weighted average price of \$2.17 per share and received total gross proceeds of \$29.9 million (\$29.0 million net of \$0.9 million of commissions payable by the Company). These sales were effected pursuant to the Company’s registration statement on Form S-3 (File No. 333-222364), which was declared effective by the SEC on January 10, 2018. The Company completed these sales pursuant to its Sales Agreement with Cantor Fitzgerald under which the Company could sell up to \$40.0 million in shares of its common stock in one or more “at-the-market” placements at prevailing market prices.

## [Table of Contents](#)

### ***Going Concern***

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”), which contemplate continuation of the Company as a going concern. The Company has not established a source of revenues sufficient to cover its operating costs, and as such, has been dependent on funding operations through the issuance of debt and sale of equity securities. Since inception, the Company has experienced significant losses and incurred negative cash flows from operations. The Company expects to incur further losses over the next several years as it develops its business. The Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy, including its planned product development efforts, preparation for its planned clinical trials, performance of clinical trials and its research and discovery efforts.

The Company’s cash and cash equivalents are not expected to be sufficient to enable the Company to meet its long-term expected plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future registrational studies. The Company has no current commitments for additional financing and may not be successful in its efforts to raise additional funds or achieve profitable operations, and there can be no assurance that additional financing will be available to the Company on commercially acceptable terms or at all. Any amounts raised will be used for further development of the Company’s product candidates, for marketing and promotion, to secure additional property and equipment and for other working capital purposes.

If the Company is unable to obtain additional capital, its long-term business plan may not be accomplished and the Company may be forced to curtail or cease operations. Further, the 2015 Credit Agreement contains a minimum liquidity covenant. The Company’s violation of its minimum liquidity covenant would constitute an event of default under the 2015 Credit Agreement. Upon an event of default, the lender may terminate the commitments under the 2015 Credit Agreement and declare the loans then outstanding under the 2015 Credit Agreement to be due and payable in whole or in part, together with any applicable fees and accrued interest thereon. If an event of default arises under the 2015 Credit Agreement, the Company may need to use cash and cash equivalents on hand to fund certain repayment commitments under the 2015 Credit Agreement.

These factors individually and collectively continue to raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements do not include any adjustments or classifications that may result from the possible inability of the Company to continue as a going concern.

## **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, all of which are wholly owned by Kadmon Holdings, Inc., have been prepared in accordance with 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 nine months ended September 30, 2019 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2019. 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, 2018.

### ***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, the accrual of research and development and clinical trial expenses, and the valuation of the Company’s investment in MeiraGTx ordinary shares (Note 11).

## [Table of Contents](#)

### ***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, 2018. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies, other than those described below.

#### ***Accounting for Leases***

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016 02, Leases ("ASC 842"), to enhance the transparency and comparability of financial reporting related to leasing arrangements. Under this new lease standard, most leases are required to be recognized on the balance sheet as right-of-use ("ROU") assets and lease liabilities. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing and uncertainty of cash flows arising from leases. Prior to January 1, 2019, GAAP did not require lessees to recognize assets and liabilities related to operating leases on the balance sheet. The new standard establishes a ROU model that requires a lessee to recognize a ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations as well as the reduction of the right of use asset. The Company has adopted the standard effective January 1, 2019 and has chosen to use the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods prior to January 1, 2019. The new standard provides a number of optional practical expedients in transition. The Company has elected to apply the 'package of practical expedients', which allow it to not reassess (i) whether existing or expired arrangements contain a lease, (ii) the lease classification of existing or expired leases, or (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. The Company has also elected to apply (i) the practical expedient, which allows it to not separate lease and non-lease components, for new leases entered into after adoption and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard. In preparation for adoption of the standard, the Company implemented internal controls to enable the preparation of financial information including the assessment of the impact of the standard. For the impact to the Company's consolidated financial statement upon adoption of the new leasing standard, see Note 8 to the unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. As of the ASC 842 effective date, the Company's incremental borrowing rate ranged from approximately 4.0%-5.6% based on the remaining lease term of the applicable leases.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

#### ***Revenue Recognition***

The Company adopted FASB ASC 606, Revenue from Contracts with Customers ("ASC 606"), on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption— i.e. by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of stockholders' equity at January 1, 2018. The Company recognizes revenue in accordance with ASC 606, 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.

## [Table of Contents](#)

### *Disaggregation of Revenue*

The following table summarizes revenue from contracts with customers for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Product sales	\$ 50	\$ 198	\$ 164	\$ 633
Other revenue	176	174	529	531
Total revenue	\$ 226	\$ 372	\$ 693	\$ 1,164

### *Product Sales*

The Company markets and distributes a portfolio of products, including ribavirin and tetrabenazine. These contracts typically include a single promise to deliver a fixed amount of product to the customer with payment due within 30 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.

As is typical in the pharmaceutical industry, gross product sales are subject to a variety of deductions, primarily representing rebates, chargebacks, returns and discounts to government agencies, wholesalers and managed care organizations. These deductions represent management's best estimates of the related reserves and, as such, judgment is required when estimating the impact of these sales deductions on gross sales for a reporting period. If estimates are not representative of the actual future settlement, results could be materially affected.

### *Other Revenue*

Other revenue generated by the Company is primarily related to a sublease agreement and an expired transition services agreement (the "TSA") with MeiraGTx. The Company performed various professional services under the TSA that supported MeiraGTx until the expiration of the TSA in April 2018. No further services were performed or TSA revenue recognized after April 2018. The Company continues to provide office space to MeiraGTx under a sublease agreement. The Company recognizes sublease income on a straight-line basis over the term of the sublease arrangement.

### *Contract Balances*

The timing of revenue recognition may differ from the timing of invoicing to customers. Accounts receivable are recorded at the invoiced amount, net of an allowance for doubtful accounts. A receivable is recognized in the period the Company delivers goods or provides services or when its right to consideration is unconditional. The Company has not recognized any assets for costs to obtain or fulfill a contract with a customer as of September 30, 2019.

### *Transaction Price Allocated to Future Performance Obligations*

ASC 606 requires that the Company disclose the aggregate amount of a transaction price that is allocated to performance obligations that have not yet been satisfied as of September 30, 2019. The guidance provides certain practical expedients that limit this requirement and the Company has various contracts that meet the practical expedients provided by ASC 606. The Company does not have any performance obligations that have not yet been satisfied as of September 30, 2019 and therefore there is no transaction price allocated to future performance obligations under ASC 606.

## [Table of Contents](#)

### ***Recent Accounting Pronouncements***

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which requires transactions in collaborative arrangements to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. The ASU also precludes entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The ASU is effective for annual or interim periods beginning after December 15, 2019. Early adoption is permitted for entities that have adopted ASC 606. The Company is evaluating the impact of adopting this standard.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (a consensus of the FASB Emerging Issues Task Force), which requires customers in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to capitalize as assets. This ASU is effective for annual or any interim periods beginning after December 15, 2019. The Company does not expect the standard to have a significant impact on its consolidated financial statements, as the Company’s cloud computing contracts are not material.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, subject to specific exceptions. This ASU is effective for annual or any interim periods beginning after December 15, 2018. The Company adopted this standard on January 1, 2019, and the standard did not have a significant impact on its consolidated financial statements as the fair value of the Company’s awards to non-employees is not material.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other, which simplifies the subsequent measurement of goodwill by eliminating “Step 2” from the goodwill impairment test. Instead of performing Step 2 to determine the amount of an impairment charge, the fair value of a reporting unit will be compared with its carrying amount and an impairment charge will be recognized for the value by which the carrying amount exceeds the reporting unit’s fair value. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not expect the standard to 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. The ASU is effective for interim and annual periods beginning after December 15, 2019, 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.

## [Table of Contents](#)

### 3. Stockholders' Equity

#### 5% Convertible Preferred Stock

The Company had 28,708 shares of 5% convertible preferred stock outstanding at September 30, 2019, 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 (the "IPO") of \$12.00 per share, or \$9.60 per share. In May 2019, a holder of 1,292 shares of 5% convertible preferred stock exercised its right to convert such shares into 154,645 shares of the Company's common stock. The Company accrued dividends on the 5% convertible preferred stock of \$0.4 million and \$1.2 million during the three and nine months ended September 30, 2019 and 2018, respectively. The Company calculated a deemed dividend of \$0.1 million on the \$0.4 million of accrued dividends during each of the three months ended September 30, 2019 and 2018, and \$0.3 million on the \$1.2 million of accrued dividends during each of the nine months ended September 30, 2019 and 2018, which is a beneficial conversion feature. The stated liquidation preference amount on the 5% convertible preferred stock totaled \$33.1 million at September 30, 2019.

#### 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. Shares issued during the period are weighted for the portion of the period during which they were outstanding. Because the Company has reported a net loss for all periods presented, diluted net loss per share of common stock is the same as basic net loss per share of common stock for those periods. 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		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
<b>Numerator – basic and diluted:</b>				
Net loss available to common stockholders - basic and diluted	\$ (62,912)	\$ (14,314)	\$ (51,183)	\$ (14,231)
<b>Denominator – basic and diluted:</b>				
Weighted average shares of common stock outstanding used to compute basic and diluted net loss per share	128,225,469	113,101,776	128,360,618	92,378,205
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.49)</b>	<b>\$ (0.13)</b>	<b>\$ (0.40)</b>	<b>\$ (0.15)</b>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Options to purchase common stock	11,999,752	9,713,427	11,999,752	9,713,427
Warrants to purchase common stock	11,999,852	11,999,852	11,999,852	11,999,852
Convertible preferred stock	3,493,002	3,476,385	3,493,002	3,476,385
<b>Total shares of common stock equivalents</b>	<b>27,492,606</b>	<b>25,189,664</b>	<b>27,492,606</b>	<b>25,189,664</b>

[Table of Contents](#)

**5. Debt**

The Company is a party to one credit agreement (the 2015 Credit Agreement) with outstanding indebtedness in the following amount (in thousands):

	September 30, 2019	December 31, 2018
Secured term debt due July 1, 2020	\$ 28,046	\$ 28,046
Total debt before debt discount	28,046	28,046
Less: Debt discount	(283)	(566)
<b>Total debt payable</b>	<b>\$ 27,763</b>	<b>\$ 27,480</b>
Debt payable, current portion	\$ 27,763	\$ —
Debt payable, long-term	\$ —	\$ 27,480

***Secured Term Debt***

***August 2015 Secured Term Debt***

In August 2015, the Company entered into a secured term loan in the amount of \$35.0 million with two lenders (the “2015 Credit Agreement”). The interest rate on the loan is LIBOR plus 9.375% with a 1% floor. As of September 30, 2019, there were five amendments to the 2015 Credit Agreement, which, among other things, have extended the maturity date and due date of principal payments under the 2015 Credit Agreement, repaid all amounts due to one of the lenders, revised terms of certain warrants issued in connection with the 2015 Credit Agreement (Note 6), and amended certain covenants, including certain non-financial developmental milestones that must be met by December 31, 2019. Each of these developmental milestones had been satisfied as of September 30, 2019. The 2015 Credit Agreement also contains a minimum liquidity covenant. As amended, the key terms of the loan require monthly payments of interest only through December 31, 2019, with principal payments in the amount of \$750,000 payable monthly beginning on January 31, 2020. Any outstanding balance of the loan and accrued interest is required to be repaid on July 1, 2020, the maturity date. The secured term loan is collateralized by a first priority perfected security interest in all the tangible and intangible property of the Company.

The Company entered into a sixth waiver agreement to the 2015 Credit Agreement in March 2019 under which the lenders under the 2015 Credit Agreement agreed to refrain from exercising certain rights under the 2015 Credit Agreement, including the declaration of a default and to forbear from acceleration of any repayment rights with respect to existing covenants. The report and opinion of our independent registered public accounting firm, BDO USA, LLP, for the year ended December 31, 2018 contains an explanatory paragraph regarding our ability to continue as a going concern, which is an event of default under the 2015 Credit Agreement.

In October 2019, the Company entered into a transaction pursuant to which it sold approximately 1.4 million ordinary shares of MeiraGTx for gross proceeds of \$22.0 million (Note 11). Pursuant to the 2015 Credit Agreement, half of the proceeds received from the sale, or \$11.0 million, were used to pay down part of the outstanding amounts owed under the 2015 Credit Agreement (Note 5). After this repayment, approximately \$17.0 million of principal remained outstanding under the 2015 Credit Agreement.

The minimum payments required on the outstanding balances of the 2015 Credit Agreement at September 30, 2019 are (in thousands):

	2015 Credit Agreement	
2019	\$	—
2020		28,046
	<b>\$</b>	<b>28,046</b>

## [Table of Contents](#)

The following table provides components of interest expense and other related financing costs (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Interest expense	\$ 836	\$ 830	\$ 2,516	\$ 2,720
Amortization of deferred financing costs, debt discount and debt premium	95	47	283	960
<b>Interest expense</b>	<b>\$ 931</b>	<b>\$ 877</b>	<b>\$ 2,799</b>	<b>\$ 3,680</b>

## 6. Financial Instruments

### Equity Issued Pursuant to Credit Agreements

In connection with the 2015 Credit Agreement (Note 5), 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 September 30, 2019, 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 \$0.6 million at September 30, 2019 and approximately \$0.5 million at December 31, 2018.

The Company used the Black-Scholes pricing model to value the warrant liability at September 30, 2019 with the following assumptions: risk-free interest rate of 1.6%, expected term of 2.9 years, expected volatility of 71.0% and a dividend rate of 0%. The change in fair value of the 2015 Warrants was approximately \$0.1 million for both the three and nine months ended September 30, 2019, and approximately \$(0.2) million and \$(0.1) million for the three and nine months ended September 30, 2018, respectively. None of these instruments had been exercised as of September 30, 2019 and December 31, 2018.

### Other Warrants

In connection with a sale of common stock by the Company in March 2017, warrants to purchase 2,707,138 shares of common stock were issued at an exercise price of \$4.50 per share. During April 2018, warrants to purchase 119,047 shares of common stock were exercised for which the Company received proceeds of \$0.5 million. The remaining 2,588,091 warrants expired in April 2018. These warrants included a cash settlement option requiring the Company to record a liability for the fair value of the warrants at the time of issuance and at each reporting period, with any change in the fair value reported as other income or expense. The change in the fair value of these warrants was \$(0.7) million for the nine months ended September 30, 2018. As these warrants expired in April 2018, no change in fair value was recorded for these warrants after April 2018.

### Fair Value of Long-term Debt

The Company maintained a long-term secured debt balance of \$27.5 million at December 31, 2018. Because the secured debt will become due on July 1, 2020 and monthly principal payments of \$750,000 will become due starting January 31, 2020, it has been recorded as long-term secured debt at December 31, 2018. At September 30, 2019, the outstanding secured debt of \$27.8 million due in the first and second quarter of 2020 was recorded as short-term secured debt. As such, the Company did not maintain a long-term secured debt balance at September 30, 2019. The underlying agreements for these balances were negotiated with third parties on an arms-length basis, at an interest rate which is considered to be in line with overall market conditions.

[Table of Contents](#)

**Fair Value Classification**

The Company held certain liabilities that are required to be measured at fair value on a recurring basis. Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The table below represents the values of the Company’s financial instruments at September 30, 2019 and December 31, 2018 (in thousands):

Description	Fair Value Measurement Using Significant Other Observable Inputs (Level 2)	
	September 30, 2019	December 31, 2018
Warrants	\$ 594	\$ 524
<b>Total</b>	<b>\$ 594</b>	<b>\$ 524</b>

The table below represents a roll-forward of Level 2 financial instruments from January 1, 2018 to September 30, 2019 (in thousands):

	Significant Other Observable Inputs (Level 2)
<b>Balance at January 1, 2018</b>	<b>\$ 1,952</b>
Change in fair value of financial instruments	(1,525)
Fair value of warrants modified in the Fifth Amendment	111
Exercise of warrants recorded as liability	(14)
<b>Balance at December 31, 2018</b>	<b>\$ 524</b>
Change in fair value of financial instruments	70
<b>Balance at September 30, 2019</b>	<b>\$ 594</b>

The Level 2 inputs used to value the Company’s financial instruments were determined using prices that can be directly observed or corroborated in active markets. 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 and therefore the Company has classified the fair value of this liability as a Level 2 liability in the table above.

**Warrants Outstanding**

The following table summarizes information about warrants outstanding at September 30, 2019 and December 31, 2018:

	Warrants	Weighted Average Exercise Price
Balance, December 31, 2018	11,999,852	\$ 5.95
Granted	—	—
Exercised	—	—
Forfeited	—	—
Balance, September 30, 2019	11,999,852	\$ 5.95

## [Table of Contents](#)

### 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 regularly reviews the expiration dates of its inventories and maintains a reserve for inventories that are probable to expire before shipment. Inventories recorded on the Company's consolidated balance sheets are net of a reserve for expirable inventory of \$2.9 million and \$2.2 million at September 30, 2019 and December 31, 2018, respectively. The Company expensed inventory that it believes will not be sold prior to reaching its expiration date totaling \$0.9 million during the nine months ended September 30, 2019 and totaling less than \$0.1 million and \$0.3 million during the three and nine months ended September 30, 2018, respectively. The Company did not record any such expense during the three months ended September 30, 2019. If the amount and timing of future sales differ from management's assumptions, adjustments to the estimated inventory reserves may be required.

#### *Inventories Produced in Preparation for Product Launches*

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when positive results have been obtained for the clinical trials that the Company believes are necessary to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and the Company has determined it is probable that these capitalized costs will provide some future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications and the compilation of regulatory applications. The Company closely monitors the status of each product within the regulatory approval process, including all relevant communication with regulatory authorities. If the Company is aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized.

For inventories that are capitalized in preparation of product launch, anticipated future sales, expected approval date and shelf lives are evaluated in assessing realizability. The shelf life of a product is determined as part of the regulatory approval process; however, in evaluating whether to capitalize pre-launch inventory production costs, the Company considers the product stability data of all of the pre-approval production to date to determine whether there is adequate expected shelf life for the capitalized pre-launch production costs.

In September 2019, the U.S. Food and Drug Administration ("FDA") approved the Company's generic trientine hydrochloride capsules USP, 250 mg. In October 2019, the FDA approved CLOVIQUE™ (trientine hydrochloride capsules, USP), the Company's room-temperature stable, branded generic product. Trientine hydrochloride is used for the treatment of Wilson's disease in patients who are intolerant of penicillamine. CLOVIQUE™ is the first FDA-approved trientine product in a portable blister pack that offers room temperature stability for up to 30 days, potentially providing patients more convenience. Accordingly, the pre-launch costs of these products are realizable as the Company expects the inventory will be sold or used prior to expiration. The Company maintained \$0.2 million and \$0.9 million of trientine hydrochloride inventory at September 30, 2019 and December 31, 2018, respectively.

Inventories are comprised of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	\$ 60	\$ —
Work-in-process	123	886
Finished goods, net	31	39
<b>Total inventories</b>	<b>\$ 214</b>	<b>\$ 925</b>

## [Table of Contents](#)

### 8. Leases

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective transition approach allowed under ASU 2018-11, Leases (Topic 842: Targeted Improvements), which releases companies from presenting comparative periods and related disclosures under ASC 842 and requires a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption (Note 2). The Company is party to six operating leases for office or laboratory space and three finance leases for office IT equipment. The Company's finance leases are immaterial both individually and in the aggregate. The Company has elected to apply the short-term lease exception to all leases of one year or less. As of September 30, 2019, this exception applied to two operating leases for office space, which are each for a term of one year. Further, the Company has applied the guidance in ASC 842 to its corporate office and laboratory leases and has determined that these should be classified as operating leases. Consequently, as a result of the adoption of ASC 842, the Company recognized a ROU lease asset of approximately \$22.7 million with a corresponding lease liability of approximately \$27.0 million based on the present value of the minimum rental payments of such leases. In accordance with ASC 842, the beginning balance of the ROU lease asset was reduced by the existing deferred rent liability at inception of approximately \$4.3 million. In the consolidated balance sheets at September 30, 2019, the Company has a ROU asset balance of \$20.5 million and a current and non-current lease liability of \$3.9 million and \$20.8 million, respectively, relating to the ROU lease asset. The balance of both the ROU lease asset and the lease liabilities primarily consists of future payments under the Company's office lease in New York, New York.

The Company is party to an operating lease in New York, New York for office and laboratory space for its headquarters. The lease commenced in October 2010, its initial term is set to expire in February 2021, and the Company opened a secured letter of credit with a third party financial institution in lieu of providing a security deposit of \$2.0 million, which letter of credit is included in restricted cash at September 30, 2019. As of September 30, 2019, there were six amendments to this lease agreement, which altered office and laboratory capacity and extended the lease term through October 2025, with total lease cost of \$1.2 million and \$3.5 million for the three and nine months ended September 30, 2019, respectively. This office lease contains the ability to extend portions of the lease at fair market value but does not have any renewal options.

The Company is party to an operating lease in Warrendale, Pennsylvania for the Company's specialty-focused commercial operation. In March 2019, the Company entered into an amendment to this lease, which extended the lease term to September 30, 2022 with two five-year renewal options, which would extend the term to September 30, 2032, if exercised. Rental payments under the renewal period would be at market rates determined from the average rentals of similar tenants in the same industrial park. The option to renew this office lease was not considered when assessing the value of the ROU asset because the Company was not reasonably certain that it would assert its option to renew the lease. Total lease cost for this lease was \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2019, respectively.

In August 2015, the Company entered into an operating office lease agreement in Cambridge, Massachusetts for the Company's clinical office effective January 2016 and expiring in April 2023. The Company opened a secured letter of credit with a third party financial institution in lieu of providing a security deposit of \$0.1 million, which letter of credit is included in restricted cash at September 30, 2019. The Company is also party to an operating lease for laboratory space in Princeton, New Jersey, which expires in February 2021. Neither of these office leases contain any renewal options. Total lease cost for these leases was \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2019, respectively.

[Table of Contents](#)

Quantitative information regarding the Company's leases for the three and nine months ended September 30, 2019 is as follows (in thousands):

Lease Cost	Classification	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost <sup>(a)</sup>	SG&A expenses	\$ 1,156	\$ 3,478
Variable lease cost	SG&A expenses	358	989
Sublease income <sup>(b)</sup>	Other revenue	(179)	(529)
<b>Net Lease Cost</b>		<b>\$ 1,335</b>	<b>\$ 3,938</b>
<b>Other Information</b>			
Operating cash flows paid for amounts included in the measurement of lease liabilities		\$ 1,150	\$ 3,498
Operating lease liabilities arising from obtaining ROU assets		127	212
Weighted average remaining lease term (years)		5.7	5.7
Weighted average discount rate		4.1%	4.1%

(a) Includes short-term lease costs and finance lease costs, which are immaterial.

(b) Includes sublease income related to MeiraGTx (Note 11).

Future lease payments under noncancellable leases are as follows (in thousands) at September 30, 2019:

Year ending December 31,	Operating Leases	Finance Leases
2019	\$ 1,205	\$ 22
2020	4,833	48
2021	4,937	6
2022	4,844	—
2023	4,153	—
Thereafter	7,732	—
<b>Total Lease Payments</b>	<b>\$ 27,704</b>	<b>\$ 76</b>
Less: Imputed Interest	(3,093)	(8)
<b>Total Lease Liabilities</b>	<b>\$ 24,611</b>	<b>\$ 68</b>

Note: As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

Future minimum rental payments under noncancellable leases are as follows (in thousands) at December 31, 2018:

Year ending December 31,	Amount
2019	\$ 4,672
2020	4,204
2021	4,177
2022	4,286
2023	4,153
Thereafter	7,731
<b>Total</b>	<b>\$ 29,223</b>

## [Table of Contents](#)

### 9. Fixed Assets

Fixed assets consisted of the following (in thousands):

	Useful Lives (Years)	September 30, 2019	December 31, 2018
Leasehold improvements	4-8	\$ 10,397	\$ 10,187
Office equipment and furniture	3-15	1,289	1,529
Machinery and laboratory equipment	3-15	3,455	3,247
Software	1-5	3,971	3,831
Construction-in-progress	–	45	45
		19,157	18,839
Less accumulated depreciation and amortization		(16,429)	(15,185)
<b>Fixed assets, net</b>		<b>\$ 2,728</b>	<b>\$ 3,654</b>

Depreciation and amortization of fixed assets totaled \$1.4 million and \$1.1 million for the nine months ended September 30, 2019 and 2018, respectively, and \$0.5 million and \$0.4 million for the three months ended September 30, 2019 and 2018, respectively. Unamortized computer software costs were \$0.4 million and \$0.7 million at September 30, 2019 and December 31, 2018, respectively. The amortization of computer software costs amounted to \$0.3 million and \$0.1 million for the nine months ended September 30, 2019 and 2018, respectively, and \$0.1 million for each of the three months ended September 30, 2019 and 2018.

### 10. Goodwill

The Company's goodwill relates to the 2010 acquisition of Kadmon Pharmaceuticals, LLC, a Pennsylvania limited liability company that was formed in April 2000. There were no changes in the carrying amount of goodwill for the nine months ended September 30, 2019 or the year ended December 31, 2018.

### 11. Investment in MeiraGTx

On June 12, 2018, MeiraGTx completed its initial public offering (the "MeiraGTx IPO") whereby it sold 5,000,000 ordinary shares at an initial public offering price of \$15.00 per ordinary share. MeiraGTx, an exempted company under the laws of the Cayman Islands, is a clinical-stage biotechnology company developing novel gene therapy treatments for a wide range of inherited and acquired disorders for which there are no effective treatments available. The shares began trading on the Nasdaq Global Select Market on June 7, 2018 under the symbol "MGTX."

Prior to the MeiraGTx IPO, for the period beginning January 1, 2018 through June 12, 2018, the Company recorded its share of MeiraGTx's net loss under the equity method of accounting of \$1.2 million. The Company had no remaining basis in any of the investments held in MeiraGTx prior to the MeiraGTx IPO. Upon completion of the MeiraGTx IPO, the Company's investment was diluted to a 13.0% ownership in MeiraGTx common stock and the Company no longer had the ability to exert significant influence over MeiraGTx. The Company discontinued the equity method of accounting for its investment in MeiraGTx on June 12, 2018 and determined that the remaining investment was an equity security accounted for in accordance with ASC 321, Investments – Equity Securities, at the date the investment no longer qualified for the equity method of accounting. ASC 321 requires the investment to be recorded at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. As the Company's investment in MeiraGTx's ordinary shares had a readily determinable market value, the Company recorded an unrealized gain of \$40.5 million for the three and nine months ended September 30, 2018 related to the fair value of its ownership of ordinary shares of MeiraGTx. As of September 30, 2019 and December 31, 2018, the Company maintained a 9.7% and 12.9% ownership, respectively, in the ordinary shares of MeiraGTx with a fair value of \$56.4 million and \$34.1 million, respectively. As of December 31, 2018, the investment was recorded as a noncurrent investment in equity securities since depending on certain circumstances, the Company could, at times, have been deemed to be an affiliate of MeiraGTx. During the third quarter of 2019 the affiliate restrictions on the resale of these securities were removed and, accordingly, the Company's investment in MeiraGTx has been recorded as a current investment in equity securities as of September 30, 2019. The Company has recorded an unrealized gain (loss) on the MeiraGTx ordinary shares investment of \$(38.6) million and \$22.3 million for the three and nine months ended September 30, 2019, respectively. The investment in MeiraGTx is valued using Level 1 inputs, which includes quoted prices in active markets for identical assets in accordance with the fair value

## [Table of Contents](#)

hierarchy (Note 6). The Company has not realized any gains related to the investment in ordinary shares of MeiraGTx as of September 30, 2019. In October 2019, the Company entered into a transaction pursuant to which it sold approximately 1.4 million ordinary shares of MeiraGTx for gross proceeds of \$22.0 million. After consummation of the transaction, the Company held approximately 5.7% of the outstanding ordinary shares of MeiraGTx.

The Company was party to a TSA with MeiraGTx, which expired in April 2018. Upon expiration of the TSA, the Company continued to provide office space to MeiraGTx. On October 1, 2018, the Company and MeiraGTx entered into a sublease agreement, which was effective from October 1, 2018 for a period of two months and is automatically renewed on a monthly basis unless MeiraGTx provides 30 days' prior written notice. The Company's accounting for this sublease as a lessor was not impacted by the adoption of the new leasing standard ASC 842 (Note 2). As part of the TSA and sublease agreement with MeiraGTx, the Company recognized \$0.1 million and \$0.4 million to other revenue during each of the three and nine months ended September 30, 2019 and 2018, respectively. The Company received cash payments of \$0.4 million and \$1.3 million, respectively, from MeiraGTx for the nine months ended September 30, 2019 and 2018. The Company had no amounts receivable from MeiraGTx at September 30, 2019 or December 31, 2018.

## **12. 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 Item 8 of its Annual Report on Form 10-K for the year ended December 31, 2018. Since the date of such financial statements, there have been no significant changes to the Company's license agreements other than described below.

### ***Jinghua***

In November 2015, the Company entered into a license agreement with Jinghua Pharmaceutical Group Co., Ltd. ("Jinghua"). Under this agreement, the Company granted to Jinghua an exclusive, royalty-bearing, sublicensable license under certain of its intellectual property and know-how to use, develop, manufacture and commercialize certain monoclonal antibodies in China, Hong Kong, Macau and Taiwan. The Company provided a notice of immediate termination of the license agreement to Jinghua on September 3, 2019. As of September 30, 2019, the Company had earned \$4 million in development milestones under this agreement.

### ***Dyax Corp. (acquired by Shire Plc in January 2016, subsequently acquired by Takeda Pharmaceuticals Co., Ltd. in 2018)***

On July 22, 2011 the Company entered into a license agreement with Dyax Corp. ("Dyax") for the rights to use the Dyax Antibody Libraries, Dyax Materials and Dyax Know-How (collectively, the "Dyax Property"). The agreement expired on its terms on September 22, 2015, but the Company retained the right to a commercial license to any research target within two years of such expiration. The Company exercised its right to a commercial license of two targets in September 2017, resulting in a license fee becoming payable to Shire Plc (who acquired Dyax) of \$1.5 million, which was recorded as research and development expense for the year ended December 31, 2017. The agreement includes the world-wide, non-exclusive, royalty-free, non-transferable license to use the Dyax Property to be used in the research field, without the right to sublicense. Additionally, the Company has the option to obtain a sublicense for use in the commercial field if any research target is obtained. The license agreement requires the Company to pay a fixed single digit royalty upon any commercial sales and also requires additional payments contingent on the achievement of certain development milestones such as receiving certain regulatory approvals and commencing certain clinical trials. None of these targets had been achieved and, as such, no assets or liabilities associated with the milestones had been recorded as of the year ended December 31, 2018. In September 2019, the Company achieved a development milestone under the license agreement, resulting in a license fee becoming payable to Takeda Pharmaceuticals Co., Ltd (which acquired Shire Plc) of \$1.5 million, which was recorded as research and development expense during the three and nine months ended September 30, 2019.

## [Table of Contents](#)

### **Contingent License Agreement Milestones**

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 \$225.9 million at September 30, 2019. Any payments made prior to FDA approval will be expensed as research and development. Payments made after FDA approval will be capitalized.

Further, 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.

### **13. Share-based Compensation**

#### **2016 Equity Incentive Plan**

A total of 11,668,905 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, 2018. This reserve automatically increased to 16,194,138 on January 1, 2019 and will automatically 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 "Board"). At September 30, 2019, there were options to purchase an aggregate of 10,709,752 shares of common stock outstanding at a weighted average price of \$5.73 per share under the 2016 Equity Plan.

Total unrecognized compensation expense related to unvested options granted under the Company's share-based compensation plan was \$4.4 million and \$6.8 million at September 30, 2019 and December 31, 2018, respectively. That expense is expected to be recognized over a weighted average period of 1.3 years and 1.5 years as of September 30, 2019 and December 31, 2018, respectively. The Company recorded share-based compensation expense under the 2016 Equity Plan of \$5.6 million and \$8.4 million for the nine months ended September 30, 2019 and 2018, respectively, and \$1.5 million and \$2.8 million for the three months ended September 30, 2019 and 2018, respectively.

The following table summarizes information about stock options outstanding, not including performance stock options, at September 30, 2019 and December 31, 2018:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2018	9,764,539	\$ 6.24	7.84	\$ —
Granted	1,593,973	1.48		
Exercised	—	—		
Forfeited	(648,760)	4.74		
Balance, September 30, 2019	10,709,752	\$ 5.73	7.50	\$ —
Options vested and exercisable, September 30, 2019	6,081,492	\$ 7.99	6.35	\$ —

There were no options exercised during the nine months ended September 30, 2019 and 2018. There were 1,593,973 stock options granted during the nine months ended September 30, 2019 with a weighted-average exercise price of \$1.48. During the nine months ended September 30, 2018, 280,924 stock options were granted with a weighted-average exercise price of \$4.62. 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:

## Table of Contents

	<u>Nine Months Ended</u> <u>September 30, 2019</u>	<u>Nine Months Ended</u> <u>September 30, 2018</u>
Weighted average fair value of grants	\$1.48	\$2.20
Expected volatility	76.19% - 77.73%	72.94% - 75.14%
Risk-free interest rate	1.41% - 2.61%	2.44% - 2.84%
Expected life (years)	5.5 - 6.0	5.5 - 6.0
Expected dividend yield	0%	0%

### *Performance Awards*

On April 3, 2018, the Company granted 1,597,500 nonqualified performance-based stock options (the “Performance Options”) to certain executive officers (each, a “Grantee”) under the 2016 Equity Plan, which represent the maximum number of Performance Options that may be earned if all three performance milestones (each, a “Performance Goal”) are achieved during the three-year period following the grant date (the “Performance Period”). The Performance Options may be earned based on the achievement of three separate Performance Goals related to the Company’s operating and research and development activities during the Performance Period, subject to the Grantee’s employment through the achievement date. If no Performance Goals are achieved during the Performance Period, the Performance Options will be forfeited. Each Performance Option was granted with an exercise price of \$4.06 per share and does not contain any voting rights. No other Performance Options have been granted under the 2016 Equity Plan.

The weighted-average fair value of the Performance Options granted was \$2.71 and was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions: risk-free interest rate of 2.67%, expected term of 6.0 years, expected volatility of 74.50% and a dividend rate of 0%.

Compensation expense for the Performance Options is recognized on a straight-line basis over the awards’ requisite service period. The Performance Options vest upon the satisfaction of both a service condition and the satisfaction of one or more performance conditions. Therefore, the Company initially determined which outcomes were probable of achievement. The Company believes that the three-year service condition (explicit service period) and all three performance conditions (implicit service periods) will be satisfied. The requisite service period would be three years as that is the longest period of both the explicit service period and the implicit service periods. The first two performance conditions were satisfied during 2018 and the third performance condition was satisfied during the third quarter of 2019.

During the year ended December 31, 2018, 307,500 Performance Options were forfeited. A total of 1,290,000 Performance Options were outstanding at both September 30, 2019 and December 31, 2018 with an exercise price of \$4.06 per share and no intrinsic value. The weighted average remaining contractual life of outstanding Performance Options at September 30, 2019 was 6.9 years. At September 30, 2019, there was \$0.6 million of total unrecognized compensation expense related to unvested Performance Options, which is expected to be recognized over a weighted-average period of 1.4 years. No Performance Options were vested at December 31, 2018. At September 30, 2019, 744,168 Performance Options had vested and no Performance Options had been exercised.

### *Stock Appreciation Rights*

A total of 835,000 stock appreciation rights (“SARs”) were outstanding at both September 30, 2019 and December 31, 2018, with an exercise price of \$3.64 per share and no intrinsic value. The weighted average remaining contractual life of outstanding SARs at September 30, 2019 was 6.8 years. Compensation expense for SARs is recognized on a straight-line basis over the awards’ requisite service period. At September 30, 2019, there was \$0.6 million of total unrecognized compensation cost related to unvested SARs that is expected to be recognized over a weighted-average period of 1.2 years. At September 30, 2019 and December 31, 2018, 398,334 and 278,335 SARs had vested, respectively, 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 September 30, 2019 and December 31, 2018. 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 September 30, 2019.

## [Table of Contents](#)

### **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, 2018. The Board elected not to increase the shares reserved for issuance under the 2016 ESPP on January 1, 2019. The Company issued 32,273 and 22,958 shares to employees under the 2016 ESPP during the nine months ended September 30, 2019 and 2018, respectively. In October 2019, the Company issued 56,346 shares to employees under the 2016 ESPP. No meaningful compensation expense was recognized for the ESPP during the nine months ended September 30, 2019 and 2018.

### **14. Accrued Expenses**

Short-term accrued expenses at September 30, 2019 and December 31, 2018 include the following (in thousands):

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
Commission payable	\$ 2,395	\$ 2,395
Compensation, benefits and severance	3,430	3,848
Research and development	5,251	4,847
Other	2,502	2,418
Total accrued expenses	<u>\$ 13,578</u>	<u>\$ 13,508</u>

#### **Commission payable**

The Company recorded \$2.4 million in accrued liabilities at both September 30, 2019 and December 31, 2018 relating to commissions to third parties for Class E redeemable convertible unit raises during 2014 and 2015.

#### **Compensation, benefits and severance**

Compensation, benefits and severance represent earned and unpaid employee wages and bonuses, as well as contractual severance to be paid to former employees. At September 30, 2019 and December 31, 2018, these accrued expenses totaled \$3.4 million and \$3.8 million, respectively.

In August 2019, the Company entered into a Separation Agreement and General Release (the "Separation Agreement") with Steven N. Gordon, Esq., Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer, and Corporate Secretary of the Company. The Separation Agreement provides that Mr. Gordon will receive, among other things, \$0.9 million in aggregate cash payments (including reimbursement of certain of Mr. Gordon's expenses) over 18 months. At September 30, 2019, \$0.6 million of severance payable to Mr. Gordon was recorded as accrued expenses while \$0.2 million was recorded as other long-term liabilities. The full terms of Mr. Gordon's separation are set forth as an exhibit to this Quarterly Report on Form 10-Q, and this summary is qualified by the full terms set forth in that exhibit.

Separately, a separation agreement with Dr. Samuel D. Waksal, which expired on February 8, 2019, contained severance payments and certain supplement conditional payments. The Company has not recorded any expense related to these conditional payments as of September 30, 2019 as none of the conditional payments were met as of the expiration of the agreement on February 8, 2019.

#### **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. At September 30, 2019 and December 31, 2018, accrued research and development expenses for which the Company has not yet been invoiced totaled \$5.3 million and \$4.8 million, respectively.

## [Table of Contents](#)

### **15. Commitments and Contingencies**

The Company's commitments 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, 2018. Since the date of such financial statements, there have been no material changes to the Company's commitments other than certain non-cancellable minimum batch commitments to purchase KD034 inventory through 2023. These commitments include \$0.4 million for 2019, \$0.5 million for 2020, \$0.4 million for 2021 and \$0.3 million for both 2022 and 2023. Further, the Company's commitments related to lease agreements are disclosed in Note 8.

The Company has been 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 have been 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. The Company has no significant contingencies related to legal proceedings at September 30, 2019.

### **16. Related Party Transactions**

The Company's related party transactions 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, 2018. Since the date of such financial statements, there have been no changes to the Company's related party transactions other than those related to MeiraGTx (Note 11).

### **17. 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.

The Tax Cuts and Jobs Act (the "Tax Act") was enacted in December 2017. The Tax Act reduces the U.S. federal corporate tax rate from 35 percent to 21 percent, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, creates new taxes on certain foreign earnings and reduces the orphan drug tax credit. In accordance with the Tax Act, the Company determined it necessary to reduce the recorded deferred tax liability by \$0.6 million during the nine months ended September 30, 2018 to allow naked credit deferred tax liabilities to be used as a source of taxable income in the future. This change in deferred tax liability was recognized as income tax benefit in the consolidated financial statements of operations for the nine months ended September 30, 2018. There was no change in deferred tax liability for the three and nine months ended September 30, 2019 and no income tax expense was recorded for the three and nine months ended September 30, 2019.

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 September 30, 2019 and December 31, 2018. At December 31, 2018, the Company had unused federal and state NOL carryforwards of \$460.3 million and \$404.3 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. These carryforwards expire at various dates through December 31, 2037, with the exception of approximately \$44.0 million of federal NOL carryforwards that will not expire. The 20-year limitation was eliminated for losses generated after January 1, 2018, giving the taxpayer the ability to carry forward losses indefinitely. However, NOL carryforwards arising after January 1, 2018, will now be limited to 80 percent of taxable income.

## [Table of Contents](#)

The use of the Company's NOL carryforwards may, however, be subject to limitations as a result of an ownership change. A corporation undergoes an "ownership change," in general, if a greater than 50% change (by value) in its equity ownership by one or more five-percent stockholders (or certain groups of non-five-percent stockholders) over a three-year period occurs. After such an ownership change, the corporation's use of its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income is subject to an annual limitation determined by the equity value of the corporation on the date the ownership change occurs multiplied by a rate determined monthly by the Internal Revenue Service. This rate for October 2019 equals 1.77 percent. The Company experienced ownership changes under Section 382 of the Internal Revenue Code of 1986, as amended, in 2010, 2011 and 2016, but the Company did not reduce the gross deferred tax assets related to the NOL carryforwards because the limitations do not hinder the Company's ability to potentially utilize all of the NOL carryforwards.

The Company is likely to experience another ownership change in the future, possibly in 2019, as a result of shifts in stock ownership due to any future equity offerings. A renewed ownership change will likely materially and substantially reduce the Company's ability to fully utilize the NOL carryforwards and, consequently, will likely reduce the gross deferred tax assets related to the NOL carryforwards. If an ownership change occurred and if the Company earned net taxable income, its ability to use the pre-change NOLs to offset U.S. federal taxable income would be subject to these limitations, which could potentially result in increased future tax liability compared to the tax liability the Company would incur if the use of NOL carryforwards were not so limited.

### **18. Subsequent Events**

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

#### **Joint Venture with BioNova Pharmaceuticals Ltd.**

In November 2019, the Company announced a strategic partnership with BioNova Pharmaceuticals Ltd. ("BioNova") to form a joint venture to exclusively develop and commercialize KD025, the Company's lead product candidate, for the treatment of graft-versus-host-disease ("GVHD") in the People's Republic of China. The joint venture, BK Pharmaceuticals Limited, is domiciled in Hong Kong with shared oversight between the Company and BioNova.

Under the terms of the transaction agreements, the Company will receive an upfront payment and is eligible to receive development, regulatory and commercial milestone payments upon the occurrence of specified events. In aggregate, the upfront payment and potential milestones could total up to \$45.0 million over the term of the agreements. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of KD025 for GVHD in China.

## [Table of Contents](#)

### **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 included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2018. 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 this Quarterly Report on Form 10-Q (including in the section titled “Forward-Looking Statements”) 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, with a near-term clinical focus on inflammatory and fibrotic diseases, as well as immuno-oncology. We leverage our 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 our small molecule and biologics platforms. We believe that we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. We expect to continue to progress our clinical candidates and have further clinical trial events to report in the remainder of 2019 and in 2020.

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 have never been profitable and had an accumulated deficit of \$320.8 million at September 30, 2019. Our net losses were \$62.4 million and \$49.6 million for the three and nine months ended September 30, 2019, respectively, and \$13.8 million and \$12.7 million for the three and nine months ended September 30, 2018, respectively.

Although our commercial business generates revenue, the revenues generated for the three and nine months ended September 30, 2019 and 2018 were not significant, and we expect to incur significant losses for the foreseeable future and expect these losses to increase as we continue our development of, and seek regulatory approvals for, our additional product candidates, hire additional personnel and initiate commercialization of any products that receive regulatory approval. We anticipate that our expenses will increase substantially if, or as, we:

- invest significantly to further develop our most advanced product candidates;
- initiate clinical trials and preclinical studies for our other product candidates;
- seek regulatory approval for any of our product candidates that successfully complete clinical trials;
- continue to invest in our research discovery platforms;
- seek to identify and develop additional product candidates;
- scale up our sales, marketing and distribution infrastructure and product sourcing capabilities;
- acquire or in-license other product candidates and technologies;
- scale up our operational, financial and management information systems and personnel, including personnel to support our product development;
- make milestone or other payments under any in-license agreements; or
- maintain, expand and protect our intellectual property portfolio.

## [Table of Contents](#)

### **Components of Statement of Operations**

The components of our statement of operations are disclosed in the audited financial statements for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 7, 2019 with the Securities Exchange Commission (“SEC”). Since the date of such financial statements, there have been no significant changes to the components of our statement of operations.

### **Critical Accounting Policies and Significant Judgments 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 accounting principles generally accepted in the United States of America (“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. On an ongoing basis, we evaluate our estimates and judgments, including those related to share-based compensation, the accrual of research and development and clinical trial expenses and the valuation of our investment in MeiraGTx. 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.

#### ***Critical Accounting Policies***

Our significant accounting policies are disclosed in our audited financial statements for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 7, 2019 with the SEC. Since the date of such financial statements, there have been no changes to our significant accounting policies except for the change in lease accounting upon adoption of ASC 842 see Note 2 and Note 8 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.

[Table of Contents](#)

**Results of Operations**

*Three and Nine Months Ended September 30, 2019 and 2018*

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
	(in thousands)		(in thousands)	
<b>Revenues</b>				
Net sales	\$ 50	\$ 198	\$ 164	\$ 633
Other revenue	176	174	529	531
Total revenue	226	372	693	1,164
Cost of sales	73	59	149	361
Write-down of inventory	—	20	932	265
Gross profit	153	293	(388)	538
Operating expenses:				
Research and development	13,227	11,918	43,326	31,876
Selling, general and administrative	10,174	9,668	27,101	26,730
Total operating expenses	23,401	21,586	70,427	58,606
Loss from operations	(23,248)	(21,293)	(70,815)	(58,068)
Total other (expense) income	(39,147)	7,494	21,172	44,771
Income tax benefit	—	—	—	562
Net loss	\$ (62,395)	\$ (13,799)	\$ (49,643)	\$ (12,735)
Deemed dividend on convertible preferred stock	517	515	1,540	1,496
Net loss attributable to common stockholders	\$ (62,912)	\$ (14,314)	\$ (51,183)	\$ (14,231)

*Revenues*

The decrease in total revenue on a quarterly basis was primarily attributable to a decline in sales of tetrabenazine of approximately \$0.1 million for the three months ended September 30, 2019 as compared to the three months ended September 30, 2018. Total revenue also included service and sublease revenue from MeiraGTx Holdings plc (“MeiraGTx”) of \$0.1 million for each of the three months ended September 30, 2019 and 2018.

The decrease in total revenue on a year-to-date basis was primarily attributable to the decline in sales of tetrabenazine from \$0.4 million for the nine months ended September 30, 2018 to \$0.1 million for the nine months ended September 30, 2019. Total revenue also included sublease revenue from MeiraGTx of \$0.4 million for each of the nine months ended September 30, 2019 and 2018.

*Cost of sales and write-down of inventory*

The decrease in cost of sales was primarily attributable to the decline in net sales revenue for each of the three and nine months ended September 30, 2019 and 2018.

The increase in inventory write-downs during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was related to write-downs of our KD034 inventory based on our expectation that such inventory will not be sold prior to reaching its product expiration date.

*Research and development expenses*

The increase in research and development expenses for the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 was primarily related to development of our most advanced product candidate, KD025.

The increase in research and development expenses for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was primarily related to development of our most advanced product candidate, KD025, as well as the development of KD033 and KD045.

## [Table of Contents](#)

### *Selling, general and administrative expenses*

The increase in selling, general and administrative expenses for the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 was primarily related to legal expenses, offset by a slight decrease in employee compensation expense.

### *Total other (expense) income*

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
	(in thousands)		(in thousands)	
Interest expense	\$ (836)	\$ (830)	\$ (2,516)	\$ (2,720)
Amortization of deferred financing costs and debt discount and premium	(95)	(47)	(283)	(960)
Change in fair value of financial instruments	(126)	198	(70)	802
Loss on equity method investment	—	—	—	(1,242)
Unrealized (loss) gain on equity securities	(38,634)	7,564	22,304	48,072
Interest income	418	534	1,622	742
Other income	126	75	115	77
<b>Total other (expense) income</b>	<b>\$ (39,147)</b>	<b>\$ 7,494</b>	<b>\$ 21,172</b>	<b>\$ 44,771</b>

For the three and nine months ended September 30, 2019, other (expense) income consisted primarily of unrealized (losses) gains related to our investment in MeiraGTx ordinary shares of \$(38.6) million and \$22.3 million, respectively, and interest income of \$0.4 million and \$1.6 million, respectively, partially offset by a change in the fair value of financial instruments of \$0.1 million and \$0.1 million, respectively, and interest expense and other costs related to our debt of \$0.9 million and \$2.8 million, respectively.

For the three and nine months ended September 30, 2018, other income consisted primarily of a change in the fair value of financial instruments of \$0.2 million and \$0.8 million, respectively, and unrealized gains related to our investment in MeiraGTx ordinary shares of \$7.6 million and \$48.1 million, respectively, partially offset by interest expense and other costs related to our debt of \$0.9 million and \$3.7 million for the three and nine months ended September 30, 2018, respectively.

### *Income tax benefit*

No income tax expense was recorded for the three and nine months ended September 30, 2019. The Tax Cuts and Jobs Act (the "Tax Act") was enacted in December 2017. In accordance with the Tax Act, we determined it was necessary to reduce our recorded deferred tax liability by \$0.6 million during the second quarter of 2018 to allow naked credit deferred tax liabilities to be used as a source of taxable income in the future. The change in deferred tax liability was recognized as income tax benefit in our consolidated financial statements of operations for the nine months ended September 30, 2018.

### *Deemed dividend*

We have 28,708 shares of 5% convertible preferred stock outstanding, 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 the Company's IPO of \$12.00 per share, or \$9.60 per share. In May 2019, the holders of 1,292 shares of 5% convertible preferred stock exercised their right to convert their convertible preferred shares into 154,645 shares of the Company's common stock. The Company accrued dividends on the 5% convertible preferred stock of \$0.4 million and \$1.2 million during the three and nine months ended September 30, 2019 and 2018, respectively. The Company calculated a deemed dividend of \$0.1 million on the \$0.4 million of accrued dividends during each of the three months ended September 30, 2019 and 2018, and \$0.3 million on the \$1.2 million of accrued dividends during each of the nine months ended September 30, 2019 and 2018, which is a beneficial conversion feature. The stated liquidation preference amount on the 5% convertible preferred stock totaled \$33.1 million at September 30, 2019.

## [Table of Contents](#)

### Liquidity and Capital Resources

#### Sources of Liquidity

Since our inception through September 30, 2019, we have raised net proceeds from the issuance of equity and debt. At September 30, 2019, we had \$28.0 million of outstanding loans under the 2015 Credit Agreement, which matures in July 2020. As of the date hereof, we are not in default under the terms of the 2015 Credit Agreement. We maintained cash and cash equivalents of \$66.1 million at September 30, 2019.

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

	Nine Months Ended	
	September 30,	
	2019	2018
	(unaudited)	
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (63,947)	\$ (52,586)
Investing activities	(430)	(811)
Financing activities	35,769	99,231
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (28,608)</u>	<u>\$ 45,834</u>

#### Operating Activities

The net cash used in operating activities was \$63.9 million for the nine months ended September 30, 2019, and consisted primarily of a net loss of \$49.6 million adjusted for \$11.5 million in net non-cash items, including unrealized gain on equity securities of \$22.3 million, offset by the depreciation and amortization of fixed assets and right-of-use lease assets of \$3.9 million, amortization of deferred financing costs and debt discount of \$0.3 million, write-down of inventory of \$0.9 million, change in fair value of financial instruments of \$0.1 million and share-based compensation expense of \$5.6 million, as well as a net decrease in operating assets and liabilities of \$2.7 million. Once adjusted for the non-cash items above, the cash used in operating activities for the nine months ended September 30, 2019 was primarily driven by selling, general and administrative expenses of \$18.8 million, research and development expense related to the advancement of our clinical product candidates of \$42.1 million and interest paid on our debt of \$2.5 million.

The net cash used in operating activities was \$52.6 million for the nine months ended September 30, 2018, and consisted primarily of a net loss of \$12.7 million adjusted for \$61.5 million in non-cash items, including the depreciation and amortization of fixed assets of \$1.1 million, amortization of deferred financing costs, debt discount and debt premium of \$1.0 million, loss on equity method investment of \$1.2 million, unrealized gain on equity securities of \$48.1 million, change in deferred tax liability of \$0.6 million, and share-based compensation expense of \$8.4 million, as well as a net decrease in operating assets and liabilities of \$2.4 million. The significant items in the change in operating assets and liabilities include a decrease of \$0.4 million in accounts payable, accrued expenses and other liabilities, an increase in prepaid and other assets of \$1.1 million due to timing of payments for certain services, and a decrease in inventories of \$1.1 million, partially offset by a decrease in accounts receivable of \$0.2 million due to timing of collections from our customers. The net loss, adjusted for non-cash items was primarily driven selling, general and administrative expenses of \$26.7 million, research and development expense related to the advancement of our clinical product candidates of \$31.9 million and interest paid on our debt of \$2.8 million, partially offset by unrealized gain on our investment in MeiraGTx ordinary shares of \$48.1 million.

#### Investing Activities

Net cash used in investing activities was \$0.4 million for the nine months ended September 30, 2019, consisting of costs related to leasehold improvements at our clinical office in Cambridge, Massachusetts and the purchase of laboratory equipment. Net cash used in investing activities was \$0.8 million for the nine months ended September 30, 2018 consisting of costs related to the purchase of property and equipment, primarily related to in-house software and laboratory equipment.

#### Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019 was \$35.8 million, consisting primarily of net proceeds from the issuance of common stock under the Sales Agreement of \$35.7 million. Net

## [Table of Contents](#)

cash provided by financing activities for the nine months ended September 30, 2018 was \$99.2 million, consisting primarily of proceeds from the issuance of common stock in our June 2018 public offering of shares of our common stock.

### **Future Funding Requirements**

We expect our expenses to increase compared to prior periods in connection with our ongoing activities, particularly as we continue research and development, continue and initiate clinical trials and seek regulatory approvals for our product candidates. In anticipation of regulatory approval for any of our product candidates, we expect to incur significant pre-commercialization expenses related to product sales, marketing, distribution and manufacturing.

The expected use of our cash and cash equivalents at September 30, 2019 represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, as well as any additional collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of our existing cash and cash equivalents. In addition, we anticipate the need to raise additional funds from the issuance of additional equity securities and monetization of assets, and our management will retain broad discretion over the allocation of those funds as well.

### **Contractual Obligations and Commitments**

There have been no material changes in our contractual obligations and commitments during the nine months ended September 30, 2019 from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2018 and those disclosed in Note 15 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Further, our commitments related to lease agreements are disclosed in Note 8 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### **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 and Exchange Act of 1934, as amended, 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 principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended). 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 principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

[Table of Contents](#)

***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 Securities and Exchange Act of 1934, as amended) occurred during the fiscal quarter ended September 30, 2019 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**

None.

**Item 1A. Risk Factors**

As a "smaller reporting company", we are not required to provide the information required by this Item.

**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**

*Appointment of New Executive Vice President, General Counsel and Corporate Secretary*

On August 30, 2019, Steven N. Gordon, Esq. notified the Company that he would be resigning from his role as Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer, and Corporate Secretary of the Company, effective immediately, in order to pursue other opportunities. In connection with his departure, the Company entered into a Separation Agreement and General Release (the "Separation Agreement") with Mr. Gordon. In consideration for the releases provided by Mr. Gordon in the Separation Agreement, and for his compliance with certain confidentiality, cooperation and other obligations, the Separation Agreement provides that Mr. Gordon will receive, among other things: (i) aggregate cash payments (including reimbursement of certain of Mr. Gordon's expenses) of \$900,000 over 18 months, (ii) accelerated vesting with respect to all outstanding stock options and appreciation rights covering the Company's common stock that are subject to time-based vesting requirements and would have otherwise vested had Mr. Gordon continued to be employed by the Company, (iii) an extension of the exercise period of Mr. Gordon's options and appreciation rights to acquire Company common stock to a total of 24 months and (iv) payment of continuing COBRA coverage for a period of 18 months. The full terms of Mr. Gordon's separation are set forth as an exhibit to this Quarterly Report on Form 10-Q, and this summary is qualified by the full terms set forth in that exhibit.

Upon the effectiveness of Mr. Gordon's resignation, the Board of Directors of the Company approved the appointment of Gregory S. Moss, Esq. to the position of Executive Vice President, General Counsel and Corporate Secretary of the Company. Mr. Moss will also serve as the Company's Chief Compliance Officer.

Mr. Moss joined the Company in 2012 and from 2015 until August 30, 2019, served as its Senior Vice President, Deputy General Counsel. Prior to joining the Company, Mr. Moss worked as a solicitor in the Corporate Risk practice group of one of Australia's leading law firms and at a boutique legal practice and hedge fund in New York City. Mr. Moss holds a Bachelor of Arts and Bachelor of Laws (BA/LLB) from Macquarie University, Sydney, Australia.

As a result of Mr. Moss's appointment as Executive Vice President, General Counsel and Corporate Secretary, Mr. Moss entered into an employment agreement pursuant to which he was granted an option to purchase 300,000 shares of common stock, receives an annual base salary of \$450,000 and is eligible for an annual cash bonus target of 35% of his base salary.

[Table of Contents](#)

**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.

[Table of Contents](#)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	<a href="#">Restated Certificate of Incorporation of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on August 5, 2019).</a>
3.2	<a href="#">Certificate of Designations of Kadmon Holdings, Inc. creating the 5% Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).</a>
3.3	<a href="#">Bylaws of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).</a>
10.1*	<a href="#">Separation Agreement and General Release between Kadmon Corporation, LLC and Steven N. Gordon, effective as of August 30, 2019.</a>
10.2*	<a href="#">Employment Agreement between Kadmon Corporation, LLC and Gregory S. Moss, effective as of August 30, 2019.</a>
31.1*	<a href="#">Certification of Principal 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.</a>
31.2*	<a href="#">Certification of Principal 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.</a>
32.1**	<a href="#">Certifications 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.</a>
32.2**	<a href="#">Certifications 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.</a>
101*	The following materials from the Kadmon Holdings, Inc. Form 10-Q for the quarter ended September 30, 2019, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018, (ii) Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018, (iii) Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018, and (iv) Notes to the Financial Statements.
*	Filed herewith.
**	Furnished herewith.



**SEPARATION AGREEMENT AND GENERAL RELEASE**

This Separation Agreement and General Release (this “Agreement”), entered into as of August 29, 2019 and effective as of August 30, 2019, is entered into by and between Steven N. Gordon (“Employee” or “you”) and Kadmon Corporation, LLC, a Delaware limited liability company (together with Kadmon Holdings, Inc., a Delaware corporation (“Parent”), the “Company”), on behalf of itself and its past and present parent entities, and its or their subsidiaries, divisions, affiliates and related business entities (collectively, the “Company Entities”).

SECTION 1. Concluding Employment. Pursuant to your notice of resignation, dated August 29, 2019 (the “Separation Date”), you voluntarily resigned from all employment with the Company and any other positions you may have held as an officer, employee, or otherwise, of any of the other Company Entities. As a result, the Separation Date was the termination date of your employment for purposes of participation in and coverage under all compensation or benefit plans and programs sponsored by or through the Company Entities except as otherwise provided herein. You acknowledge and agree that after the Separation Date you shall not represent, and since the Separation Date you have not represented, yourself as being a director, officer, employee, agent or representative of any Company Entity for any purpose, and you shall not, uninvited, enter the premises of any of the Company Entities at any time. You agree that, as of the date of this Agreement, the Company has made all payments due to you for any earned but unpaid base salary and previously submitted un-reimbursed business expenses (in accordance with usual Company policies, guidelines and practices, including, without limitation, the Company’s Business Travel and Expense Policy). You will retain any previously vested benefits (including equity compensation awards) in accordance with the terms of the applicable benefit plan and/or applicable grant or award agreement. For the avoidance of doubt, your vested stock options and vested stock appreciation rights shall be treated as if your termination of employment was without “cause” within the meaning of the Company’s 2016 Equity Incentive Plan (the “EIP”) (and, for the avoidance of doubt, only for such purposes under the EIP, and not for any other purpose) and, the Company confirms that with respect to your awards under the Company’s 2014 Long Term Incentive Plan (“LTIP”), you have satisfied the Service Vesting Date requirement set forth and defined in your Amended and Restated Award Notification and Grant Agreement

SECTION 2. Payment.

(a) In exchange for your execution of a release and waiver of claims against the Released Parties (as defined below) and your compliance with the other terms and conditions of this Agreement, the Company agrees to: (i) pay you in the aggregate amount of \$800,000 (the “Payment Amount”), payable in bi-weekly equal installments over an eighteen-month period, effective as of the Separation Date (the “Payment Period”). IRS Forms W-2 will issue regarding these payments, and they will be subject to all applicable withholding taxes; (ii) if you timely elect continued coverage under the

---

Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”), the Company will pay on your behalf medical, dental and vision health insurance premiums necessary to continue your coverage (including coverage for eligible dependents, if applicable) for the entirety of the Payment Period (the “Benefit Period”); and (iii) On September 1, 2019, pay legal fees to your counsel, Jonathan S. Sack of Sack & Sack LLP in the amount of \$100,000, for which IRS Forms 1099-MISC will issue and which will not be subject to any deductions or withholdings. Notwithstanding anything to the contrary herein, in the event that you materially and incurably breach any of your obligations under this Agreement, the Company will immediately cease to have any obligations to make (x) any further payments under Section 2(i) above or (y) any further medical insurance premium payments under Section 2(ii) above. If you become eligible for Health Insurance by any means during the Benefit Period, you must immediately notify the Company and the Company shall immediately cease making any payments related to Health Insurance as set forth hereunder.

(b) In further exchange for your execution of a release and waiver of claims against the Released Parties and your compliance with the other terms and conditions of this Agreement, the Company agrees to accelerate the vesting of all unvested options and stock appreciation rights granted to you pursuant to the Company’s 2016 Employee Equity Incentive Plan (as amended) prior to the Separation Date. The Company further agrees to extend the exercise period with respect to all such options and stock appreciation rights granted to you for two (2) years following the Separation Date.

SECTION 3. Acknowledgement. You acknowledge and agree that the payments and other benefits provided pursuant to this Agreement: (a) are in full discharge of any and all liabilities and obligations of the Company to you, monetarily or with respect to employee benefits or otherwise, including but not limited to any and all obligations arising under any alleged written or oral employment agreement (including, without limitation, the Employment Agreement, dated July 1, 2015, by and between you and the Company (the “Employment Agreement”), which is the only Employment Agreement in force regarding your relationship with the Company), policy, plan or procedure of the Company and/or any alleged understanding or arrangement between you and the Company and (b) exceeds any payment, benefit or other thing of value to which you might otherwise be entitled under any policy, plan or procedure of the Company and/or any agreement between you and the Company, written, oral or otherwise.

SECTION 4. Release. (a) Mutual General Release. You, on behalf of yourself and your agents, heirs, executors, administrators, successors and assigns, hereby RELEASE AND FOREVER DISCHARGE the Company Entities, as well as any and all of their predecessors, successors and assigns and any and all of their respective past or present directors, officers, employees, investors, shareholders, partners, fiduciaries, agents, trustees, administrators, attorneys and insurers, whether acting as agents for the Company or in their individual capacities (collectively the “Released Parties”), from any and all claims, damages, complaints, grievances, causes of action, suits, liabilities, demands and expenses (including attorneys’ fees) of any nature whatsoever, both at law and in equity (except those expressly reserved herein), whether known or unknown, now existing or which may result from the existing state of things, which you now have or

---

ever had against the Released Parties up to and including the date hereof. In particular, without limitation of the foregoing, the Released Parties are specifically released from and held harmless from any and all claims arising out of or related to your employment relationship with the Company Entities, including, without limitation, your separation from such employment. It is your intention that this Section 4 constitute a full and final general release of all such claims and that this release be as broad as possible. This Section 4 does not release or waive any rights or claims that may arise after the date hereof. By signing this Agreement, the Company hereby releases and forever discharges you with respect to and from any and all commitments, responsibilities, obligations, claims, damages, complaints, grievances, causes of action, suits, liabilities, demands and expenses (including attorneys' fees) of any nature whatsoever, both at law and in equity (except those expressly reserved herein), whether known or unknown, now existing or which may result from the existing state of things, which the Company now has or ever had against you up to and including the date hereof, except that the Company does not release, discharge, or waive claims against you relating to criminal behavior or other intentional misconduct or gross negligence of which the Company is not currently aware.

(b) Scope of Release. Without limiting the foregoing in any way, your release and waiver includes, but is not limited to, any rights or claims you may have under: the Age Discrimination in Employment Act of 1967 (29 U.S.C. § 621, *et seq.*); Title VII of the Civil Rights Acts of 1964; 42 U.S.C. § 1981; the Family and Medical Leave Act; the Fair Labor Standards Act; the Equal Pay Act; the Rehabilitation Act of 1973 and the Americans with Disabilities Act; the Employee Retirement Income Security Act of 1974; Worker Adjustment and Retraining Notification Act of 1988; the Older Workers Benefit Protection Act; the National Labor Relations Act; the Sarbanes-Oxley Act of 2002; the Dodd-Frank Wall Street Reform and Consumer Protection Act; the claims under the New York State Human Rights Law and the New York City Administrative Code, the Genetic Information Nondiscrimination Act; the Unfair Business Practices Act; and any other federal, state or local laws or regulations concerning employment, the termination thereof or prohibiting employment discrimination, harassment or retaliation. Your release and waiver also includes any claims against the Company or the Released Parties based on contract or tort, claims for defamation, libel, invasion of privacy, intentional or negligent infliction of emotional distress, wrongful termination, constructive discharge, breach of contract, breach of the covenant of good faith and fair dealing, breach of fiduciary duty and fraud, including claims involving your Employment Agreement, all other employment agreements ever executed between you and the Company, and all other promises, employment contracts, oral contracts, or any other agreements between you and the Company. You agree that you shall never file a lawsuit or other complaint challenging the reasonableness, validity or enforceability of this Section 4. You waive and release any claim that you have or may have to reemployment after the Separation Date.

(c) No Lawsuits, Complaints, or Claims. You waive your right to file any charge or complaint against the Company or any of the Released Parties arising out of your employment or separation from such employment or any facts occurring prior to the date hereof before any federal, state or local court or any federal, state or local administrative agency, except where such waivers are prohibited by law. By signing this

---

Agreement, you represent that you have not filed any such claims, causes of action or complaints. **Notwithstanding the foregoing, you do not waive or release any claim which cannot be validly waived or released by private agreement. Specifically, nothing in this Agreement shall prevent you from filing a charge or complaint with, or from participating in, an investigation or proceeding conducted by the Securities and Exchange Commission (the “SEC”), Equal Employment Opportunity Commission (the “EEOC”), the New York State or New York City Human Rights Commissions (collectively, the “HRC”) or any other federal, state or local agency charged with the enforcement of any laws applicable to the Company or, directly or indirectly, your employment with the Company. However, you understand that by signing this Agreement, you waive the right to recover any damages or to receive other relief in any claim or suit brought by or through the EEOC, the HRC or any other state or local deferral agency on your behalf to the fullest extent permitted by law, but expressly excluding any award or other relief available from the SEC. As of the date hereof, you represent and warrant that you have not made any such report, or caused or encouraged any other person to make such a report, as described above in this Section 4. This Agreement is not intended to, and shall not be interpreted in any manner that limits or restricts you from exercising any legally protected whistleblower rights (including pursuant to Section 21F of the Securities Exchange Act of 1934 (“Section 21F”)) or receiving an award for information provided to any government agency under any legally protected whistleblower rights. You are further hereby notified that you may be entitled to immunity from liability for certain disclosures of trade secrets under the Defend Trade Secrets Act, 18 U.S.C. § 1833(b). You acknowledge that you have no pending workers’ compensation claims and that this Agreement is not related in any way to any claim for workers’ compensation benefits, and that you have no basis for such a claim.**

(d) Rights Not Relinquished. In executing this Agreement, you shall not relinquish or release (i) any right to any vested benefits under any benefit plans or arrangements maintained by any of the Company Entities and any rights you may have under COBRA, (ii) any available right to indemnification under any applicable directors and officers liability insurance policy, indemnity agreement, applicable state and federal law and the Company’s articles of incorporation and bylaws and (iii) your right to enforce this Agreement.

(e) Waiver of Claims Under the Age Discrimination in Employment Act. You recognize that, in signing this Agreement, you are waiving your right to pursue any and all claims under the Age Discrimination in Employment Act, 29 U.S.C. § 626 *et seq.* (“ADEA”) arising prior to the date that you execute this Agreement. You understand that you may take twenty-one (21) days from the date this Agreement is presented to you to consider whether to execute this Agreement. You are advised that you may wish to consult with an attorney prior to execution of this Agreement. Once you have executed this Agreement, you may revoke the Agreement at any time during the seven (7) day period following your execution of the Agreement. After seven (7) days have passed following your execution of this Agreement, your execution of this Agreement shall be final and irrevocable.

---

(f) Knowing and Voluntary Execution. By signing this Agreement, you hereby acknowledge and confirm that: (i) you have read this Agreement in its entirety and understands all of its terms; (ii) by this Agreement, you have been advised in writing of the right to consult with an attorney of your choosing before executing this Agreement and have been strongly encouraged and given the opportunity to so consult with an attorney; (iii) you knowingly, freely, and voluntarily assent to all of the terms and conditions set out in this Agreement including, without limitation, the waiver, release, and covenants contained in it; (iv) you are executing this Agreement, including the waiver and release, in exchange for good and valuable consideration in addition to anything of value to which you are otherwise entitled; and (vi) you understand that the release contained in this Section 4 does not apply to rights and claims that may arise after you sign this Agreement.

#### SECTION 5. Restrictive Covenants.

(a) Non-Disparagement. You agree not to make any statements or representations, or otherwise communicate, directly or indirectly, in writing, orally, or otherwise, or take any action that may, directly or indirectly, disparage any of the Company Entities, as well as any and all of their predecessors, successors and assigns and any and all of their respective past, present or future directors, officers, employees, investors, shareholders, partners, fiduciaries, agents, trustees, administrators, attorneys and insurers, whether acting as agents for the Company or in their individual capacities (collectively, the “Company Representatives”). For the purposes of this Agreement, the term “disparage” includes, without limitation, comments or statements to the press and/or media, the Company Entities or any individual or entity with whom any of the Company Entities has a business relationship which would adversely affect in any manner (i) the conduct of the business of any of the Company Entities (including, without limitation, any business plans or prospects), (ii) the business reputation of the Company Entities or (iii) the personal reputations of any Company Representative. The Company will direct its current executive officers and directors not to make untrue statements or representations, or otherwise communicate, directly or indirectly, in writing, orally, or otherwise, or take any action that may, directly or indirectly, disparage you personally or professionally. When describing your separation of employment from the Company to third parties, the Company will describe your departure as a resignation, use words consistent in form and substance with the statement contained in Exhibit A or provide an actual copy of Exhibit A; provided, however, that the Company shall have no obligation or liability for the statements, representations or communications of its non-executive officer employees or agents. Nothing in this Agreement shall preclude you or the Company’s directors and officers from responding truthfully to a valid subpoena, cooperating with a governmental agency in connection with any investigation it is conducting, or taking any action otherwise required or permitted by law, provided that such response does not exceed that required by the law, regulation, or order. The Company and/or you shall promptly provide written notice of any such order to the other’s counsel, except as prohibited by law.

(b) Cooperation. (i) You agree that you will cooperate (1) with the Company Entities and their respective counsel in connection with any current

---

investigation, administrative proceeding or existing litigation relating to any matter that occurred during your employment in which you were involved and of which you have knowledge and (2) with the Company Entities with respect to the transition of your duties and authorities to other employees of the Company following the date hereof. The Company will provide you with reasonable compensation for any such cooperation that is provided after the eighteen month anniversary of your Separation Date not to exceed \$1,643.84 per day; provided, however, that the Company will have no obligation at any time to compensate you for cooperation provided in connection with any currently threatened or pending proceedings or litigation described in subclause (1) above.

(ii) Both parties agree that, in the event it is subpoenaed by any person or entity (including, but not limited to, any government agency) to give testimony (in a deposition, court proceeding or otherwise) which in any way relates to your employment by the Company and/or the Company Entities, it will give prompt notice of such request to the other's counsel (or her/his successor or designee), except as prohibited by law, and will make no disclosure until the other party had a reasonable opportunity to contest the right of the requesting person or entity to such disclosure.

(c) Mutual Confidentiality. The terms and conditions of this Agreement are and shall be deemed to be confidential, and shall not be disclosed by either party to any person or entity without the prior written consent of the other party, except if required by law or rule of a national securities exchange, and to a party's accountants, attorneys and/or immediate family, provided that, to the maximum extent permitted by applicable law, rule, code or regulation, they agree to maintain the confidentiality of the Agreement. Each party further represents that it has not disclosed the terms and conditions of the Agreement, or had any communications regarding the discussions or other deliberative processes of the Board with respect to this Agreement, to anyone other than the party's advisors, attorneys, accountants and/or family.

(d) Confidential Information. (i) You acknowledge that during the course of your employment with the Company Entities, you have had access to information relating to the Company Entities and their respective businesses that is not generally known by persons not employed by the Company Entities and that could not easily be determined or learned by someone outside of the Company Entities that provides the Company Entities with a competitive advantage, or that could be used to the Company Entities' disadvantage by a competitor ("Confidential Information") and that such information constitutes a valuable asset of the Company Entities. You shall not, without the prior written consent of the Company or as required by law, use or disclose or enable anyone else to use or disclose any Confidential Information of the Company Entities (whether or not developed by you), nor shall you have any communications with any outside investors of the Company as of the date hereof regarding the Company Entities and their respective businesses; provided, however, that inadvertent communications with any outside investors regarding the Company Entities and their respective businesses shall not constitute a breach of this Agreement provided that (A) such communications do not include the disclosure of Confidential Information and (B) after you have knowledge of such occurrence, you (x) immediately cease any further infringing

---

communications and (y) report all such inadvertent communications to the Company as soon as reasonably practicable. As used herein, the term “Confidential Information” includes, but is not limited to, (X) all trade secrets, confidential information and know-how, business plans, operations, products, strategies, marketing, sales, inventions, designs, costs, legal strategies, finances, employees, customers, prospective customers, licensees or licensors; information received from third parties under confidential conditions; or other valuable financial, commercial, business, technical or marketing information concerning the Company or any of the products or services made, developed or sold by the Company, but does not include information any of the Company Entities have previously intentionally disclosed to the public or is otherwise in the public domain, and (Y) the Company’s tangible and electronic documents and information used to implement, develop, produce, distribute or otherwise commercialize (1) ROCK inhibitor platforms, (2) Wilson disease-based treatments, (3) polycystic kidney disease-based treatments and (4) any of the Company’s existing commercial or development programs in place as of the date hereof. You agree not to disclose or use such Confidential Information at any time in the future except as may be required by law.

(ii) In the event that you are requested pursuant to, or required by, applicable law, rule or regulation of any governmental entity or national securities exchange, or legal process to disclose any Confidential Information, you will promptly notify the Company so that it may seek a protective order or other appropriate remedy, and you will cooperate fully with the Company in protecting Confidential Information to the extent possible under applicable law. In the event that no such protective order or other remedy is obtained, or that the Company does not waive compliance with the terms hereof applicable to such disclosure, the Company nonetheless shall be deemed to consent to the disclosure of, and you will furnish, only that portion of the Confidential Information which you are legally required to disclose and you agree to exercise all reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the information so disclosed.

(iii) Notwithstanding anything in this Agreement to the contrary, nothing in or about this Agreement prohibits you from: (1) filing and, as provided for under Section 21F, maintaining the confidentiality of a claim with the SEC; (2) providing Confidential Information to the SEC, or providing the SEC with information that would otherwise violate this Section 5, to the extent permitted by Section 21F; (3) cooperating, participating or assisting in an SEC investigation or proceeding without notifying the Company; or (4) receiving a monetary award as set forth in Section 21F.

(iv) You acknowledge and agree that, if you are found by a court of competent jurisdiction to have violated the terms and conditions of Section 5(f), you shall be obligated to pay liquidated damages to the Company in an amount equal to the legal fees incurred by the Company in connection with such proceeding. In addition, the Company shall be entitled to obtain equitable relief, including injunctive relief, to enforce this provision and shall be entitled to retain any and all profits related to any commercialization compensation or income

---

earned by or owed to you or your affiliates, directly or indirectly, from any such violation of this Section 5(d).

(e) Return of Property. You represent that, as of the date hereof, you have returned (or have initiated the prompt return) to the Company all property of material value belonging to, procured on behalf of or paid for by the Company Entities during your employment, including but not limited to all proprietary and/or Confidential Information and that you no longer have any IT-related equipment with access to the Company network. The Company will pack and send to you, at a location of your choosing in New York State, your personal effects, which will be facilitated through the Company's human resources department in accordance with normal practice. The Company will provide you with the printer and desktop computer from your office after it has been appropriately sanitized of Company related data. You are authorized to cancel the Dropbox account under your name and permitted to stop making monthly payments thereon.

(f) Prior Acts or Omissions. You represent that, from the Separation Date through the date hereof, you have not performed any act or omission that would otherwise result in a breach of any provision of this Section 5.

(g) Definitions. The following terms have the meanings provided below.

(1) "Employee of the Company" means any employee of any Company Entity who was employed by any Company Entity at any time in the 12-month period immediately preceding any actual or attempted hiring, solicitation or making of an offer.

SECTION 6. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be illegal, void or unenforceable, such provision shall have no effect; however, the remaining provisions shall be enforced to the maximum extent possible. Further, if a court should determine that any portion of this Agreement is overbroad or unreasonable, such provision shall be given effect to the maximum extent possible by narrowing or enforcing in part that aspect of the provision found overbroad or unreasonable.

SECTION 7. Breach of Agreement. The parties agree that for any breach of this Agreement, the non-breaching party may seek all relief available under the law or at equity, including, if by you, recoupment of the Payment Amount and benefits provided pursuant to this Agreement. The parties further acknowledge that any breach of the covenants set forth in this Agreement will cause the non-breaching party irreparable harm for which there is no adequate remedy at law, and the breaching party therefore consents to the issuance of an injunction in favor of the non-breaching enjoining the alleged breach of any of those covenants by any court of competent jurisdiction.

SECTION 8. Section 409A. (a) Intent to Comply with Section 409A. Notwithstanding anything to the contrary set forth in this Agreement or any other plan,

---

policy, arrangement or agreement with any of the Company Entities (this Agreement and such other plans, policies, arrangements and agreements, collectively the “Company Plans”), it is intended that the provisions of the Company Plans comply with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder as in effect from time to time (“Section 409A”) and all provisions of the Company Plans shall be construed and interpreted in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A. However, in light of the uncertainty surrounding the proper application of Section 409A, the Company cannot make any representations or guarantees with respect to compliance with such requirements, and neither the Company nor any of the Company Entities will have any obligation to indemnify or otherwise hold you harmless from any or all of such taxes or penalties. Each payment made under this Agreement shall be designated as a “separate payment” within the meaning of Section 409A.

(b) Timing of Reimbursement Payments and Other Benefits. Except as specifically permitted by Section 409A, the benefits and reimbursements provided to you under any Company Plan during any calendar year shall not affect the benefits and reimbursements to be provided to you under any Company Plan in any other calendar year, and the right to such benefits and reimbursements cannot be liquidated or exchanged for any other benefit, in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) or any successor thereto. Furthermore, reimbursement payments shall be made to you as soon as practicable following the date that the applicable expense is incurred, but in no event later than the last day of the calendar year following the calendar year in which the underlying expense is incurred, in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) or any successor thereto. Notwithstanding anything in this Agreement to the contrary, in the event that you are deemed to be a “specified employee” within the meaning of Section 409A(a)(2)(B)(i), no payments hereunder that are “deferred compensation” subject to Section 409A and payable on account of your separation from service shall be made to you prior to the date that is six months after your Separation Date or, if earlier, your date of death. Following any applicable six month delay, all such delayed payments will be paid in a single lump sum on the first payroll date following the date that is six months after your Separation Date.

SECTION 9. Miscellaneous. (a) This Agreement is not intended, and shall not be construed, as an admission that either party or any of the Company Entities has violated any federal, state or local law (statutory or decisional), ordinance or regulation, breached any contract or committed any wrong whatsoever against the other.

(b) Should any provision of this Agreement require interpretation or construction, it is agreed by the parties that the entity interpreting or construing this Agreement shall not apply a presumption against one party by reason of the rule of construction that a document is to be construed more strictly against the party who prepared the document.

SECTION 10. Assignment. This Agreement is binding upon, and shall inure to the benefit of, the parties and their respective heirs, executors, administrators, successors and assigns. You may not assign this Agreement, or any right, remedy,

---

obligation nor liability arising hereunder, and any attempt to assign this Agreement or any right, remedy, obligation or liability hereunder shall be void *ab initio*.

SECTION 11. Governing Law. (a) This Agreement shall be construed and enforced in accordance with the laws of the State of New York without regard to the principles of conflicts of law.

SECTION 12. Entire Agreement. You understand that this Agreement constitutes the complete understanding between the Company and you, and supersedes any and all agreements, understandings, and discussions, whether written or oral, between you and any of the Company Entities, including, without limitation, the Employment Agreement; provided, however, that you agree that: (a) you shall remain subject to any non-competition agreement; confidentiality agreement, or employee invention agreement that you executed prior to commencing employment with the Company or any of the Company Entities, or during your employment with the Company (including, without limitation, the terms and conditions set forth in Appendix A to each of the LTIP, Amended and Restated Award Notification and Grant Agreements – EAR Unit Awards); and (b) all parties agree that the LTIP and your awards thereunder are not impacted by this Agreement and remain in full force and effect in their entirety. As of the date hereof, you represent and warrant that you have complied with the terms of each of the agreements described in this Section 12 and no breach or default has occurred thereunder as a result of your actions or activities. No other promises or agreements shall be binding unless in writing and signed by both the Company and you after the date hereof.

SECTION 13. Headings and Captions. The headings and captions herein are provided for reference and convenience only. They shall not be considered part of the Agreement and shall not be employed in the construction of the Agreement.

---

Dated: August 29, 2019

By: /s/ Steven N. Gordon  
Steven N. Gordon

---

Dated: August 29, 2019

**KADMON CORPORATION, LLC**

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

---



## EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT**, effective August 30, 2019 (the “Agreement”), is entered into between **Kadmon Corporation, LLC**, a Delaware limited liability company (the “Company”), and **Gregory S. Moss**, an individual with a residence at [ADDRESS REDACTED] (the “Employee”). Each of Company and Employee a “Party” and collectively, the “Parties”.

**WHEREAS**, the Parties have previously entered into that certain Employment Agreement dated as of June 18, 2012 (as amended, the “Previous Agreement”); and

**WHEREAS**, the Parties now wish to supersede in its entirety the Previous Agreement, effective August 30, 2019 (the “Effective Date”), by entering in this Agreement.

**NOW, THEREFORE**, in consideration of the Employee’s employment by the Company, and for other good and valuable consideration set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Employment.** The Employee shall be employed as Executive Vice President, General Counsel and Corporate Secretary, and Chief Compliance Officer, and shall have the duties, responsibilities and authority as may from time to time be assigned to him by the Company’s Chief Executive Officer (the “CEO”), currently Dr. Harlan W. Waksal, M.D., and/or the Board of Directors (the “Board”) of Kadmon Holdings, Inc., the Company’s parent company, that are consistent with such positions in a company of the size and nature of the Company. The Employee will report to the CEO and the Board. The Employee agrees while he is employed by the Company to devote his full business time and attention to the activities of the Company and to not engage in other employment without the prior written consent of the CEO. The Employee agrees to perform his duties hereunder diligently and to use his best efforts, skill and ability to promote the interests of the Company and its affiliates.
  2. **Term.** The term of the Employee’s employment under this Agreement shall be effective as of the date hereof and shall continue until terminated by either Party in accordance with Section 5 hereof (the “Term”). Upon termination for any reason, the Parties agree that the provisions of Sections 4 and 5 shall survive.
  3. **Compensation and Benefits**
    - a) **Base Salary.** Beginning as of the Effective Date, the Company shall pay the Employee a base salary at the rate of \$450,000.00 per year (the “Base Salary”). All salary shall be paid in accordance with the Company’s regular payroll schedule and subject to required withholdings.
    - b) **Guaranteed Incentives:** The Company will cause Kadmon Holdings, Inc., to grant to employee options to purchase 300,000 shares of stock (the “Options”) of Kadmon Holdings, Inc., as soon as administratively practicable following the execution hereof (the “Grant Date”). The Options will vest in three (3) equal tranches on each of the first three (3) anniversaries of the Grant Date. Other than as described in this Section 3(b), the issuance and vesting of the Options will be contingent upon Employee’s continued employment with the Company and the Options will be subject to the terms and conditions of the Company’s 2016 Equity Incentive Compensation Plan, as amended from time to time, a copy of which will be made available to Employee as part of your onboarding materials. The terms of any option awards granted to you on or after the Effective Date
-

(including but not limited to the Options described in this paragraph) will provide that if you are involuntarily terminated without Cause (as defined in this Agreement) or if you terminate your employment with Good Reason (as defined in this Agreement), then you will be eligible to exercise any options that have vested as of your termination date until the earlier of: (i) the second anniversary of your termination date, and (ii) the date the options would otherwise expire pursuant to their terms.

- c) **Discretionary Bonus.** Employee will be eligible for a year-end target bonus of 35% of the Base Salary (“Target Bonus”), based on Company performance and Employee performance. The evaluation of both Company performance and Employee performance, and the amount of any bonus paid hereunder (the “Discretionary Bonus”), will be at the discretion of the Board’s Compensation Committee, with input from Dr. Waksal, and no guarantees relating to such cash bonus are being made by the Company. Employee must be employed on the date the bonus is paid in order to receive any Discretionary Bonus described hereunder.
- d) **Incentive Compensation.** The Employee will be entitled to participate in the Company’s annual, year-end incentive compensation plans, subject to the terms of such plans. The decision as to the amounts of any incentive compensation, including grants of equity, to be awarded shall be made by the Company, but in any event shall be consistent in type and amount as are given to other members of executive management generally.
- e) **Benefits.** The Employee will be entitled to coverage under or participation in all benefit plans provided to members of executive management of the Company. The Company may, in its sole discretion, at any time amend or terminate its benefit plans. The Employee shall be entitled to no fewer than four weeks of paid vacation per calendar year, to be used in accordance with the Company’s then-current vacation policies.

#### 4. Covenants

- a) **Return of Documents.** Immediately upon the Company’s request or promptly upon the end of the Employee’s employment, for whatever reason, the Employee shall deliver to the Company any property of the Company or any of its affiliates (including, but not limited to, documents prepared or made by the Employee) which may be in the Employee’s possession, including, but not limited to, materials, memoranda, notes, records, reports, designs, sketches, plans, programs, printouts, or other documents as well as all copies thereof and files related thereto.
  - b) **Confidentiality.** The Employee agrees to hold all Proprietary Information (as defined below) in strict confidence during the term of and following the Employee’s employment under this Agreement. “Proprietary Information” includes, by way of example but without limitation, the following information relating to the Company or any of its affiliates or any customer, client or business partner of the Company or any of its affiliates:
    - i. working methods and operations, methodologies, marketing plans and strategies (including internal and external growth strategies), sales and financial reports, customer lists, trade secrets, copyrightable materials, patentable materials, programs, processes, plans, product ideas, techniques, designs, models, formulas, data, know-how and other information used in research, developmental, marketing, sales, and operational activities; and
    - ii. any commercial or technical information, improvements, or things which may be communicated to the Employee or which the Employee may learn by virtue of his employment by the Company, or of which the Employee may have gained knowledge, or discovered, invented, or perfected while employed by the Company, including without limitation any ideas or processes relating to the development, operation, or improvement of any software or other program, product or proposed
-

product, tool, article, or process sold, licensed, distributed, maintained or contemplated by the Company or any of its affiliates (or their respective customers).

Notwithstanding the foregoing, Proprietary Information shall not include information that (a) is publicly known as of the date of this Agreement or (b) becomes publicly known after the date of this Agreement other than by means in violation of this Agreement or another obligation of confidentiality.

The Employee agrees to never, directly or indirectly, disclose or otherwise communicate to any person, firm, corporation, or other entity or to use for himself (except while the Employee is employed by the Company, and solely in pursuit of his activities as an employee of the Company), any Proprietary Information.

- c) **Developments.** The Employee agrees to disclose promptly to the Company any and all Developments (as defined below) which are made, invented, developed or discovered by the Employee, either singly or jointly with others, in the course of his employment by the Company. The Employee also agrees that such Developments are works made for hire and are or shall become the exclusive property of the Company, and that he hereby relinquishes and assigns any and all intellectual property rights and or other rights in the Developments to the Company, including, by way of example, but without limitation, rights of identification or authorship and rights of approval with respect to modifications and limitations on subsequent modifications. In order to effectuate ownership by the Company when necessary, the Employee agrees, without further consideration:
- i. to immediately upon the Company's request execute all documents and make all assignments necessary to vest title to such Developments in the Company;
  - ii. to assist the Company in any reasonable manner to obtain for the benefit of the Company any patents or copyright applications on such Developments, in any and all countries; and
  - iii. to execute when requested any and all patent and copyright applications and any other lawful documents deemed necessary by the Company to carry out the purposes of this Agreement.

"Developments" include, by way of example but without limitation, the following: any and all inventions, improvements, discoveries, developments, results of research, or useful ideas, whether or not patentable, which relate in any manner to any products, work, or other business or proposed business of the Company or one of its affiliates or any customer, client or business partner of the Company or one of its affiliates, or to any process, apparatus, formulas, equipment, or article worked on in connection with the Employee's employment by the Company.

## 5. Termination

- a) **Death or Disability.** The Employee's employment hereunder shall terminate immediately upon his death or upon 30 days written notice by the Company to the Employee that the Employee's employment has been terminated due to the Employee's Disability. For the purposes of this Agreement, "Disability" shall mean upon the earlier of: (i) the date Employee becomes entitled to receive disability benefits under the Company's long-term disability plan; or (ii) the determination by the CEO that the Employee is physically or mentally incapacitated or impaired and has been unable, for a period of at least 90 consecutive days, to perform the duties and responsibilities contemplated under this Agreement, even with a reasonable accommodation.
-

- b) **Termination for Cause.** Employment with the Company may be terminated by the CEO or the Board immediately for Cause. In this context the term “Cause” shall mean: (i) the Employee’s conviction of a felony; (ii) any material misconduct by the Employee with respect to the Company, any affiliate of the Company, or any of their respective employees, customers, clients, business partners or suppliers; (iii) in carrying out his duties and responsibilities set forth herein, refusal, neglect or failure by the Employee to carry out, in all material respects, the legal instructions of the CEO or the Board; (iv) a material breach by the Employee of any term or provision of Section 4 of this Agreement; or (v) the Employee’s failure to comply in all material with the internal policies or procedures of the Company or its affiliates, or any laws or regulations applicable to Employee’s conduct as an employee of the Company; which in each case of clauses (ii) to (v) above, remains uncured by the Employee for 5 days following receipt by the Employee of written notice of same, which notice shall include reasonable detail as to the nature of the potential resulting Cause. However, no notice and opportunity to cure shall be required in the event of conduct by the Employee that the Company reasonably believes cannot be adequately cured.
  - c) **Termination Without Cause.** Employment may be terminated by the CEO or the Board without Cause, at any time, without prior notice.
  - d) **Resignation by Employee for Good Reason.** Employee may resign from his employment hereunder at any time if Employee has Good Reason. For purposes of this Agreement, the term “Good Reason” shall mean: (i) any material diminution in Employee’s duties or responsibilities hereunder (other than in connection with a termination of Employee’s employment), which remains uncured by the Company for 5 days following receipt by the Company of written notice of same, which notice shall include reasonable detail as to the nature of the potential resulting Good Reason; (ii) a reduction in Employee’s Base Salary; (iii) a relocation of the Company’s principal place of business outside New York City; or (iv) a material diminution in the authority, duties, or responsibilities of the supervisor to whom Employee is required to report, specifically: Dr. Waksal.
  - e) **Resignation by Employee Without Good Reason.** Employee may resign from his employment hereunder without Good Reason at any time upon written notice to the Company. Following any such notice, the Company may reduce or remove any and all of Employee’s duties, authority or responsibilities with the Company, and any such reduction or removal shall not constitute Good Reason.
  - f) **Effect of Termination.** In the event that the Employee’s employment hereunder is terminated for Cause, or Employee resigns without Good Reason, the Company shall pay the Employee his Base Salary through the date of such termination and any unreimbursed business expense (in accordance with Company policy). In the event that the Employee’s employment hereunder is terminated without Cause, or Employee resigns with Good Reason, and provided that Employee first signs and does not revoke any portion of a comprehensive release of claims against the Company, and its current and former affiliated entities and individuals, in a customary form drafted by the Company, the Company shall pay the Employee severance in an amount equal to his Base Salary and an amount equal to the greater of his Target Bonus or the previous year’s Discretionary Bonus (collectively, the “Severance”). This Severance will be combined together and paid in in equal installments, and in accordance with the Company’s regular payroll schedule, and subject to required withholdings, over the one-year period following the expiration of a seven-day revocation period set forth in the comprehensive release of claims, provided, however, that in the event Employee becomes employed by another entity or individual (and not self-
-

employed) during that one-year period, he will so notify the Company, and such employment will end the Company's obligation to make any further severance payments.

- g) **Benefits.** Subject to Employee's timely election of continuation coverage under COBRA, the Company will continue payment of Employee's medical, dental and vision insurance coverage during the twelve (12) month period following the first day of the month following the date of termination or resignation (the "Coverage Period") to the same extent that the Company paid for such coverage immediately prior to the date of termination or resignation, in a manner intended to avoid any excise tax under Section 4980D of the Internal Revenue Code of 1986, as amended (the "Code"), subject to the eligibility requirements and other terms and conditions of such insurance coverage, provided that Employee first signs and does not revoke any portion of a comprehensive release of claims against the Company, and its current and former affiliated entities and individuals, in a form drafted by the Company, and provided further that in the event Employee becomes employed by another entity or individual (and not self-employed) during that one-year period, he will so notify the Company, and such employment will end the Company's obligation to continued payments for medical, dental, and vision insurance coverage. If Employee fails to sign or revokes any portion of a comprehensive release of claims against the Company, the Employee's accrual of or participation in plans providing for medical, dental and vision insurance benefits will cease at the end of the Term, unless Employee properly and timely elects to continue medical, dental and vision insurance coverage in accordance with the continuation requirements of COBRA and pays the applicable premiums for such coverage. The Employee will not receive, as part of his termination pay pursuant to this Section 5, any payment or other compensation for any sick leave or other leave unused on the date the notice of termination or resignation is given, (or on the date the termination or resignation is otherwise effective in the event no notice is required), under this Agreement.

#### 6. Miscellaneous

- a) **Governing Law.** This Agreement will be governed by the laws of the State of New York without regard to the conflict of laws principles.
- b) **Arbitration.** The Parties agree that any dispute arising under or concerning this Agreement, the Employee's employment by the Company or any related entity, or any compensation or benefits claimed by the Employee, shall be resolved solely in a confidential proceeding before a single arbitrator in New York, New York. The arbitration will be conducted pursuant to the then current rules of the American Arbitration Association for the resolution of employment disputes. Neither Party will bring any publicity to the arbitration, including, without limitation, the existence of a dispute, any claims or defenses raised in arbitration, or the arbitration award. However, either Party may bring an action to enforce an arbitration award in the event the other Party refuses to comply with the arbitration award within thirty (30) days following its issuance.
- c) **Notices.** All notices, consents, waivers and other communications under this Agreement must be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by email (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (iii) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers of the Company and Employee as set forth in the records of the Company.
- d) **Section Headings: Construction.** The headings of sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement
-

unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

- e) **Amendments; Entire Agreement; Successors and Assigns** . Neither this Agreement nor any term hereof may be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the Party against which enforcement of such change, waiver, discharge or termination is sought. This Agreement embodies the entire agreement and the understanding among the Parties, superseding all prior agreements and understandings relating to the subject matter hereof, except the confidentiality and invention assignment agreement between you and the Company, any equity or equity-based or linked award agreements outstanding as of the Effective Date, and any Company employee benefit plan outstanding as of the Effective Date. Employee understands and agrees that this Agreement shall govern his employment with the Company and its related entities, and shall supersede in its entirety any other form of agreement, written or oral, relating to Employee's employment with the Company, except for the agreements and plans set forth in the preceding sentence . If any provision of this Agreement shall be held illegal, invalid or unenforceable, in whole or in part, such provision shall be modified to the minimum extent necessary to make it legal, valid and enforceable, and the legality, validity and enforceability of the remaining provisions shall not be affected thereby. This Agreement shall be binding upon the Company's successors and assigns.
  - f) **Non-Disparagement**. The Company's officers and directors and the Employee agree that, during the Term and thereafter (including following the end of Employee's employment for any reason) neither Party will make any statements or representations, or otherwise communicate, directly or indirectly, in writing, orally, or otherwise, or take any action that may, directly or indirectly, disparage the other Party. Nothing in this paragraph shall prohibit the Employee or the Company, or its officers or directors, from bringing an action under Section 6(b) above and providing truthful information or making truthful statements in connection with such action, or with providing truthful information or making truthful statements in connection with a subpoena or other legal process.
  - g) **Representations**. The Employee represents and warrants to the Company that (i) the execution, delivery and performance of this Agreement by the Employee does not and will not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Employee is a party or by which the Employee is bound, (ii) the Employee has had the opportunity to review the covenants contained in Section 4 with counsel, that said covenants were the result of negotiation between the parties, and that he desires to be bound by the covenants in order to obtain the compensation provided by this Agreement and (iii) upon the execution and delivery of this Agreement by the Company, this Agreement shall be the valid and binding obligation of the Employee, enforceable in accordance with its terms. The Company represents and warrants to the Employee that (i) the execution, delivery and performance of this Agreement by the Company does not and will not conflict with, breach, violate or cause a default under any its organizational documents or any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which the Company is bound, (ii) this Agreement has been duly authorized by all requisite limited liability company action on the part of the Company and (iii) upon the execution and delivery of this Agreement by the Employee, this Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms.
  - h) **Confidentiality of this Agreement**. The Employee agrees to keep confidential the terms of this Agreement. This provision does not prohibit the Employee from providing this
-

information to the Employee's attorneys or accountants for purposes of obtaining legal or tax advice or as required by law; provided that such persons are informed of the confidential nature of such information and the Employee shall be responsible for breaches of the confidentiality restrictions contained herein by such persons as if the Employee had breached such restrictions. The Company shall not disclose the terms of this Agreement except as necessary in the ordinary course of its business, as required by law or as required by any governmental or quasi-governmental entity or any self-regulatory organization.

- i) **Cooperation.** Following termination of employment with the Company for any reason, the Employee shall cooperate with the Company, as requested by the Company, to effect a transition of the Employee's responsibilities and to ensure that the Company is aware of all matters being handled by the Employee.
- j) **Counterparts.** This Agreement may be executed in separate counterparts, each of which shall be deemed to be an original and both of which taken together shall constitute one and the same agreement.
- k) **Section 409A and Taxes.** All forms of compensation paid to you by the Company, including any payments made pursuant to this Agreement, are subject to reduction (or payment by you, to the extent that additional amounts are required) to reflect applicable withholding and payroll taxes and other applicable deductions. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company related to tax liabilities arising from your compensation. The payments and benefits under this Agreement are intended, and will be construed, to be exempt from or comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"); provided, however, that nothing in this Agreement shall be construed or interpreted to transfer any liability for any tax (including a tax or penalty due as a result of a failure to comply with Section 409A) from you to the Company or to any other entity or person. Any payment to you under this Agreement that is subject to Section 409A and that is contingent on a termination of employment is contingent on a "separation from service" within the meaning of Section 409A. If, upon separation from service, you are a "specified employee" within the meaning of Section 409A, any payment under this Agreement that is subject to Section 409A and triggered by a separation from service and would otherwise be paid within six months after your separation from service will instead be paid in the seventh month following your separation from service or, if earlier, upon your death (to the extent required by Section 409A(a)(2)(B)(i)). Any taxable reimbursement due under the terms of this Agreement shall be paid no later than December 31 of the year after the year in which the expense is incurred, and all taxable reimbursements and in-kind benefits shall be provided in accordance with Treas. Reg. § 1.409A-3(i)(1)(iv). The Parties agree that if necessary to avoid non-compliance with Section 409A, they will cooperate in good faith to modify the terms of this Agreement or any applicable equity award, provided, that such modification shall endeavor to maintain the economic intent of this Agreement or any such equity award.

**IN WITNESS WHEREOF** the Parties hereto have executed this Agreement as of the date first written above.

---

**KADMON CORPORATION, LLC**

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

Date: August 30, 2019

/s/ Gregory S. Moss  
Gregory S. Moss

Date: August 30, 2019

---

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, 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: November 7, 2019

/s/ Harlan W. Waksal

Harlan W. Waksal  
President and Chief Executive Officer

---

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, 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: November 7, 2019

/s/ Steven Meehan

Steven Meehan  
Executive Vice President, Chief Financial Officer

---

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, ASADOPTED  
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 September 30, 2019 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: November 7, 2019

/s/ Harlan W. Waksal

Harlan W. Waksal  
President and Chief Executive Officer

---

**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 September 30, 2019 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: November 7, 2019

/s/ Steven Meehan

Steven Meehan  
Executive Vice President, Chief Financial Officer

---

