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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

or

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

For transition period from _____ to _____.

Commission File Number: 001-37841

Kadmon Holdings, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	KDMN	Nasdaq Global Select Market

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

The number of shares of the registrant's common stock outstanding as of November 2, 2020 was 171,512,945.

Kadmon Holdings, Inc.

Form 10-Q

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FORWARD-LOOKING STATEMENTS

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

- whether our New Drug Application for belumosudil will be accepted by the U.S. Food and Drug Administration;
- 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;
- the impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials and on various government agencies who we interact with and/or are governed by;
- our reliance on the success of our product candidates;
- the timing or likelihood of regulatory filings and approvals, especially in light of the COVID-19 pandemic;
- the benefits of U.S. Food and Drug Administration designations such as Breakthrough Therapy, and review of our New Drug Application under the FDA's Oncology Center of Excellence pilot program, Real-Time Oncology Review;
- the commercialization, pricing and reimbursement of our product candidates, if approved, and our ability to expand our sales and marketing capabilities;
- 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;
- our ability to maintain and establish strategic agreements and collaborations and the potential benefits of those arrangements;
- 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 and estimates regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements, needs for additional financing and share performance;
- litigation, including costs associated with prosecuting or defending pending or threatened claims and any adverse outcomes or settlements not covered by insurance;
- our expected use of cash and cash equivalents and other sources of liquidity;
- the future trading price of the shares of our common stock and the impact of securities analysts’ reports on these prices;

- the future trading price of our equity investments 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 under the caption “Risk Factors.”

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

PART I. FINANCIAL INFORMATION

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

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 105,949	$ 139,597
Marketable debt securities, available-for-sale	44,514	—
Accounts receivable, net	373	954
Inventories, net	28	640
Prepaid expenses and other current assets	2,240	1,416
Investment, equity securities	9,238	41,997
Total current assets	162,342	184,604
Fixed assets, net	1,620	2,444
Right of use lease asset	17,013	19,651
Goodwill	3,580	3,580
Restricted cash	2,117	2,116
Investment, at cost	2,300	2,300
Other noncurrent assets	17	103
Total assets	$ 188,989	$ 214,798
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,110	$ 9,043
Accrued expenses	10,212	14,248
Term debt - current	679	—
Lease liability - current	4,143	3,966
Warrant liabilities	1,016	1,485
Total current liabilities	28,160	28,742
Lease liability - noncurrent	16,631	19,759
Deferred tax liability	461	461
Term debt - noncurrent	2,378	—
Other long term liabilities	—	101
Total liabilities	47,630	49,063
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2020 and December 31, 2019; 28,708 shares issued and outstanding at September 30, 2020 and December 31, 2019.	44,011	42,433
Common stock, $0.001 par value; 400,000,000 shares authorized at September 30, 2020 and December 31, 2019; 171,220,592 and 159,759,996 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	171	160
Additional paid-in capital	512,904	456,211
Accumulated deficit	(415,702)	(333,069)
Accumulated other comprehensive loss	(25)	—
Total stockholders' equity	141,359	165,735
Total liabilities and stockholders' equity	$ 188,989	$ 214,798

See accompanying notes to consolidated financial statements (unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net sales	$ 339	$ 50	$ 1,227	$ 164
Other revenue	151	176	6,446	529
Total revenue	490	226	7,673	693
Cost of sales	214	73	704	149
Write-down of inventory	148	—	1,054	932
Gross profit	128	153	5,915	(388)
Operating expenses:				
Research and development	17,268	13,227	46,658	43,326
Selling, general and administrative	10,865	10,174	30,299	27,101
Total operating expenses	28,133	23,401	76,957	70,427
Loss from operations	(28,005)	(23,248)	(71,042)	(70,815)
Other income (expense) :				
Interest income	208	418	802	1,622
Interest expense	(8)	(931)	(13)	(2,799)
Change in fair value of warrant liabilities	602	(126)	469	(70)
Realized gain on equity securities	4,274	—	19,784	—
Unrealized (loss) gain on equity securities	(3,254)	(38,634)	(32,759)	22,304
Gain on extinguishment of obligation	1,626	—	1,754	—
Other (expense) income	(49)	126	(50)	115
Total other income (expense)	3,399	(39,147)	(10,013)	21,172
Loss before income tax expense	(24,606)	(62,395)	(81,055)	(49,643)
Income tax expense	—	—	—	—
Net loss	$ (24,606)	$ (62,395)	$ (81,055)	$ (49,643)
Deemed dividend on convertible preferred stock	543	517	1,578	1,540
Net loss attributable to common stockholders	$ (25,149)	$ (62,912)	$ (82,633)	$ (51,183)
Basic and diluted net loss per share of common stock	$ (0.15)	$ (0.49)	$ (0.50)	$ (0.40)
Weighted average basic and diluted shares of common stock outstanding	169,310,056	128,225,469	165,107,295	128,360,618
Other comprehensive loss:				
Net unrealized loss on available-for-sale securities	25	—	25	—
Other comprehensive loss	25	—	25	—
Comprehensive loss attributable to common shareholders	$ (25,174)	$ (62,912)	$ (82,658)	$ (51,183)

See accompanying notes to consolidated financial statements (unaudited)

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

For the Three Months Ended September 30, 2020

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, July 1, 2020	28,708	$ 43,468	171,097,067	$ 171	$ 510,171	$ —	$ (390,553)	$ 163,257
Share-based compensation expense	—	—	—	—	2,453	—	—	2,453
Common stock issued for option exercises	—	—	123,525	—	280	—	—	280
Beneficial conversion feature on convertible preferred stock	—	109	—	—	—	—	(109)	—
Accretion of dividends on convertible preferred stock	—	434	—	—	—	—	(434)	—
Other comprehensive loss	—	—	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	—	—	(24,606)	(24,606)
Balance, September 30, 2020	28,708	$ 44,011	171,220,592	$ 171	$ 512,904	$ (25)	$ (415,702)	$ 141,359

For the Three Months Ended September 30, 2019

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, July 1, 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)

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

For the Nine Months Ended September 30, 2020

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, January 1, 2020	28,708	$ 42,433	159,759,996	$ 160	$ 456,211	$ —	$ (333,069)	$ 165,735
Share-based compensation expense	—	—	—	—	7,111	—	—	7,111
Common stock issued in public offering, net	—	—	11,060,786	11	48,430	—	—	48,441
Common stock issued under ESPP plan	—	—	98,840	—	216	—	—	216
Common stock issued for warrant exercises	—	—	2,777	—	7	—	—	7
Common stock issued for option exercises	—	—	298,193	—	929	—	—	929
Beneficial conversion feature on convertible preferred stock	—	316	—	—	—	—	(316)	—
Accretion of dividends on convertible preferred stock	—	1,262	—	—	—	—	(1,262)	—
Other comprehensive loss	—	—	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	—	—	(81,055)	(81,055)
Balance, September 30, 2020	28,708	$ 44,011	171,220,592	$ 171	$ 512,904	$ (25)	$ (415,702)	$ 141,359

For the Nine Months Ended September 30, 2019

	Preferred stock		Common stock		Additional paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	capital	Loss	Deficit	Total
Balance, January 1, 2019	30,000	$ 42,231	113,130,817	$ 113	$ 315,710	$ —	$ (269,643)	$ 88,411
Share-based compensation expense	—	—	—	—	5,587	—	—	5,587
Common stock issued in public offering, net	—	—	16,316,805	17	35,679	—	—	35,696
Common stock issued under ESPP plan	—	—	32,273	—	73	—	—	73
Beneficial conversion feature on convertible preferred stock	—	308	—	—	—	—	(308)	—
Accretion of dividends on convertible preferred stock	—	1,232	—	—	—	—	(1,232)	—
Common stock issued upon conversion of convertible preferred stock	(1,292)	(1,856)	154,645	—	1,856	—	—	—
Net income	—	—	—	—	—	—	(49,643)	(49,643)
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)

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (81,055)	$ (49,643)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premium and discounts on available-for-sale securities	122	—
Depreciation and amortization of fixed assets	1,263	1,356
Non-cash operating lease cost	2,638	2,495
Write-down of inventory	1,054	932
Amortization of debt discount	—	283
Share-based compensation	7,111	5,587
Change in fair value of warrant liabilities	(469)	70
Net unrealized loss (gain) on equity securities	12,975	(22,304)
Gain on extinguishment of obligation	(1,754)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	581	1,003
Inventories, net	(442)	(221)
Prepaid expenses and other assets	(738)	346
Accounts payable	2,919	(1,402)
Lease liability	(2,951)	(2,763)
Accrued expenses and other liabilities	(2,383)	314
Net cash used in operating activities	(61,129)	(63,947)
Cash flows from investing activities:		
Purchases of investment debt securities	(44,661)	—
Purchases of fixed assets	(291)	(430)
Proceeds from sale of equity securities	19,784	—
Net cash used in investing activities	(25,168)	(430)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	48,441	35,696
Proceeds from issuance of term debt	3,057	—
Proceeds from exercise of options	929	—
Proceeds from issuance of ESPP shares	216	73
Proceeds from exercise of warrants	7	—
Net cash provided by financing activities	52,650	35,769
Net decrease in cash, cash equivalents and restricted cash	(33,647)	(28,608)
Cash, cash equivalents and restricted cash, beginning of period	141,713	96,856
Cash, cash equivalents and restricted cash, end of period	$ 108,066	$ 68,248
Components of cash, cash equivalents and restricted cash		
Cash and cash equivalents	105,949	66,132
Restricted cash	2,117	2,116
Total cash, cash equivalents and restricted cash	108,066	68,248
Supplemental cash flow disclosures:		
Cash paid for interest	$ —	$ 2,514
Non-cash investing and financing activities:		
Beneficial conversion feature on convertible preferred stock	316	308
Accretion of dividends on convertible preferred stock	1,262	1,232
Unpaid fixed asset additions	148	—
Operating cash flows paid for amounts included in the measurement of lease liabilities	3,609	3,498
Operating lease liabilities arising from obtaining right-of-use assets	—	212
Common stock issued upon conversion of convertible preferred stock	—	1,856
Cumulative effect of change in accounting principle - ASC 842 adoption	—	27,083

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

Liquidity

The Company maintained cash, cash equivalents and marketable debt securities of $150.5 million at September 30, 2020. The Company had an accumulated deficit of $415.7 million and working capital of $134.2 million at September 30, 2020. The Company entered into a Sales Agreement with Cantor Fitzgerald & Co. ("Cantor") in August 2017 under which the Company could sell up to $50.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the "ATM Program"). Any such sales would be effected pursuant to the Company's registration statement on Form S-3 (File No. 333-233766), which was declared effective by the Securities Exchange Commission ("SEC") on September 24, 2019. In May 2020, the Company sold 11,060,786 shares of common stock at a weighted average price of $4.52 per share through the ATM Program and received total net proceeds of $48.5 million (net of $1.5 million of commissions payable by the Company to Cantor). Under this registration statement, the Company registered to sell, in one or more transactions, up to $200.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The Company had sold securities totaling an aggregate of $151.5 million pursuant to this registration statement as of September 30, 2020. In May 2020, the Company entered into a single transaction pursuant to which it sold approximately 1.1 million ordinary shares of MeiraGTx Holdings plc ("MeiraGTx") for gross proceeds of $15.5 million. In July 2020, the Company entered into an additional single transaction pursuant to which it sold approximately 0.3 million ordinary shares of MeiraGTx for gross proceeds of $4.2 million. The Company expects that its cash, cash equivalents and marketable debt securities will enable it to advance its planned commercial launch efforts for belumosudil, if approved, advance certain of its other pipeline product candidates, including KD033 and KD045, and provide for other working capital purposes.

Management's plans include continuing to finance operations through the issuance of debt and sale of additional equity securities, monetization of assets, including the Company's ownership of MeiraGTx ordinary shares, 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 also filed a shelf registration statement on Form S-3 (File No. 333-238969) on June 5, 2020, which was declared effective by the SEC on June 16, 2020. Under this registration statement, the Company may sell, in one or more transactions, up to $300.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units, an amount which includes $50.0 million of shares of its common stock that may be issued in the ATM Program under the Sales Agreement with Cantor. The Company had not sold any securities pursuant to this registration statement as of September 30, 2020.

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, cash equivalents and marketable debt securities will not 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 registration studies. Additionally, the COVID-19 pandemic has had a negative near-term impact on capital markets and may impact the Company's ability to access capital.

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 (which is not assured at this time), its long-term business plan may not be accomplished and the Company may be forced to curtail or cease operations. These factors individually and collectively 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, 2020 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2020.

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, 2019.

Use of Estimates

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

Critical Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements included in Item 8 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies, other than those described below.

Debt

On April 15, 2020, the Company received the proceeds from a loan in the amount of approximately $3.1 million (the "Loan") from PNC Bank, National Association, as lender, pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The Loan matures on April 15, 2022 and bears interest at a rate of 1% per annum. On August 20, 2020, the loan was amended so that, commencing August 15, 2021, the Company is required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 15, 2022 the principal amount outstanding on the Loan as of October 15, 2020. The Loan is evidenced by a promissory note dated April 15, 2020 (the "Note"), which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

The application for these funds required the Company to certify in good faith that the then current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to take into account its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The Company made this good faith assertion based upon various factors, including the degree of uncertainty introduced to the capital markets as a result of the COVID-19 pandemic and the Company's dependency on its ability to raise capital to fund ongoing operations.

All or a portion of the Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application by the Company upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of eligible and documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for the Loan, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive the Loan, the Company may be required to repay the Loan in its entirety and/or be subject to additional penalties. In the event the Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal.

The Company used all proceeds from the Loan to retain employees, maintain payroll and make lease, rent and utility payments. Under the terms of the loan, the Company may be eligible for full or partial loan forgiveness. The Company has begun preparations to apply for forgiveness, however, no assurance is provided that the Company will obtain forgiveness for any portion of the Loan.

The Company has accounted for the Loan as a debt instrument in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 470, *Debt*. At September 30, 2020, $0.7 million of principal payments due in the third quarter of 2021 have been recorded as short-term debt and the remaining balance of $2.4 million is recorded as long-term debt. The Company does not expect to incur any material interest expense under the Loan.

Cash, Cash Equivalents and Marketable Debt Securities

The Company considers all highly liquid securities with an original or remaining maturity of three months or less at the time of acquisition to be cash equivalents.

Marketable debt securities are considered to be available-for-sale and are carried at fair market value. The estimated fair value of the available-for-sale marketable debt securities is determined based on quoted market prices or rates for similar instruments. Unrealized gains and losses, if any, are reported in accumulated other comprehensive income (loss). The cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in other (expense) income. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are also included in other (expense) income. Interest and dividends on available-for-sale securities are included in other income.

The Company determines the appropriate classification of its investments in debt securities at the time of purchase. All of the Company's debt securities are classified as available-for-sale and are reported as short-term or long-term based on maturity dates and whether such assets are reasonably expected to be realized in cash or sold or consumed during the normal cycle of business.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company experienced a credit loss and have the intent to sell the investment or if it is more likely than not that the Company will be required to sell the investment before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

The following table summarizes the Company's cash, cash equivalents and marketable debt securities as of September 30, 2020 and December 31, 2019:

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	$ 103,126	$ —	$ —	103,126
Corporate debt securities	2,823	—	—	2,823
Total cash and cash equivalents	105,949	—	—	105,949
Marketable debt securities:				
Corporate debt securities	44,540	2	(28)	44,514
Total marketable debt securities	44,540	2	(28)	44,514
Total cash, cash equivalents and marketable debt securities	**$ 150,489**	**$ 2**	**$ (28)**	**$ 150,463**

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	$ 139,597	$ —	$ —	139,597
Total cash and cash equivalents	139,597	—	—	139,597
Marketable debt securities:				
Corporate debt securities	—	—	—	—
Total marketable debt securities	—	—	—	—
Total cash, cash equivalents and marketable debt securities	**$ 139,597**	**$ —**	**$ —**	**$ 139,597**

At September 30, 2020, the Company had invested in 15 available-for-sale marketable debt securities that were in an unrealized loss position for less than one year and no securities in an unrealized loss position for more than 12 months. The aggregate fair value of debt securities in an unrealized loss position at September 30, 2020 was $36.7 million. The unrealized losses of less than $0.1 million related to these corporate debt securities were included in accumulated other comprehensive loss as of September 30, 2020. Unrealized losses on corporate debt securities have not been recognized into income because the issuers' bonds are of high credit quality (rated A3/A- or higher), management does not intend to sell and it is likely that management will not be required to sell the securities prior to their anticipated recovery, and the decline in fair value is largely due to market conditions and/or changes in interest rates. The issuers continue to make timely interest payments on the bonds. The fair value is expected to recover as the bonds approach maturity and the Company does not believe any unrealized losses represent other-than-temporary impairments.

Revenue Recognition

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

Disaggregation of Revenue

The Company's revenues have primarily been generated through product sales, collaborative research, development and commercialization license agreements, and other service agreements. The following table summarizes revenue from contracts with customers for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Product sales	$ 339	$ 50	$ 1,227	$ 164
License revenue	—	—	6,000	—
Other revenue	151	176	446	529
Total revenue	$ 490	$ 226	$ 7,673	$ 693

Product Sales

These contracts typically include a single promise to deliver a fixed amount of product to the customer with payment due within 30-60 days of shipment. Revenues are recognized when control of the promised goods is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods. The timing of revenue recognition may differ from the timing of invoicing to customers. The Company has not recognized any assets for costs to obtain or fulfill a contract with a customer as of September 30, 2020.

License Revenue

License revenue consists of a milestone payment earned pursuant to a joint venture and license agreement entered into with Meiji Seika Pharma Co., Ltd ("Meiji") to develop belumosudil (KD025) in Japan (Note 9). As of December 31, 2019, the Company had one performance obligation related to a license agreement with Meiji that had not yet been satisfied and for which the upfront cash payment had not been received. The transaction price of $6.0 million was allocated to the single combined performance obligation under the contract and the performance obligation was completed during the first quarter of 2020. There are no performance obligations that have not yet been satisfied and there is no transaction price allocated to future performance obligations as of September 30, 2020.

Other Revenue

The other revenue generated by the Company is primarily related to a sublease agreement with MeiraGTx (Note 8). The Company recognizes revenue related to sublease agreements as they are performed.

Recent Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update ("ASU") No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes"*, which removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU is effective for annual or interim periods beginning after December 15, 2020, with early adoption permitted. The Company does not expect the standard to have a significant impact on its consolidated financial statements.

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 Company adopted this standard on

January 1, 2020, and the standard did not have a significant impact on its consolidated financial statements as the Company does not have any material agreements that are within the scope of this ASU.

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 ASC 350-40 to determine which implementation costs to capitalize. The Company adopted this standard on January 1, 2020, and the standard did not have a significant impact on its consolidated financial statements as the Company's cloud computing contracts are 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. For smaller reporting companies, ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted this standard on April 1, 2020, and the standard did not have a significant impact on its consolidated financial statements as the Company's goodwill is not material.

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

3. Stockholders' Equity

5% Convertible Preferred Stock

The Company had 28,708 shares of 5% convertible preferred stock outstanding at September 30, 2020, 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. The stated liquidation preference amount on the 5% convertible preferred stock totaled $34.8 million at September 30, 2020.

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 each period presented, diluted net loss per share of common stock is the same as basic net loss per shares of common stock for the three and nine months ended September 30, 2020 and 2019. 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator – basic and diluted:				
Net loss available to common stockholders - basic and diluted	$ (25,149)	$ (62,912)	$ (82,633)	$ (51,183)
Denominator – basic and diluted:				
Weighted average shares of common stock outstanding used to compute basic and diluted net loss per share	169,310,056	128,225,469	165,107,295	128,360,618
Net loss per share, basic and diluted	**$ (0.15)**	**$ (0.49)**	**$ (0.50)**	**$ (0.40)**

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Options to purchase common stock	17,357,285	11,999,752	17,357,285	11,999,752
Warrants to purchase common stock	11,917,052	11,999,852	11,917,052	11,999,852
Convertible preferred stock	3,667,651	3,493,002	3,667,651	3,493,002
Total shares of common stock equivalents	**32,941,988**	**27,492,606**	**32,941,988**	**27,492,606**

5. Financial Instruments

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

Items classified as Level 1 within the valuation hierarchy consist of the Company’s cash equivalents held in money market funds and its ownership of MeiraGTx (Note 8). The Company measures these investments at fair value determined based on Level 1 observable quoted price market inputs.

Items classified as Level 2 within the valuation hierarchy consist of the Company’s marketable debt securities and warrant liabilities. The Company estimates the fair values of the marketable debt securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Level 2 inputs used to value the Company’s warrant liabilities were determined using prices that can be directly observed 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.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value at September 30, 2020 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		Fair Value Measurements Using		
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 98,593	$ 98,593	$ —	$ —
Corporate debt securities	2,823	—	2,823	—
Short-term investments:				
Corporate debt securities	44,514	—	44,514	—
Ownership of MeiraGTx	9,238	9,238	—	—
	$ 155,168	$ 107,831	$ 47,337	$ —
Financial liabilities				
Warrant liabilities	$ 1,016	$ —	$ 1,016	$ —

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value at December 31, 2019 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		Fair Value Measurements Using		
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 136,058	$ 136,058	$ —	$ —
Short-term investments:				
Ownership of MeiraGTx	41,997	41,997	—	—
	$ 178,055	$ 136,058	$ —	$ —
Financial liabilities				
Warrant liabilities	$ 1,485	$ —	$ 1,485	$ —

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

Warrant Liabilities

In connection with a credit agreement entered into in 2015, 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, 2020, 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 $1.0 million at September 30, 2020 and approximately $1.5 million at December 31, 2019.

The Company used the Black-Scholes pricing model to value the warrant liability at September 30, 2020 with the following assumptions: risk-free interest rate of 0.1%, expected term of 1.9 years, expected volatility of 71.3% and a dividend rate of 0%. The change in fair value of the 2015 Warrants was approximately $(0.6) million and $ (0.5) million for the three and nine months ended September 30, 2020 and approximately $0.1 million for both the three and nine months ended September 30, 2019, respectively. None of these instruments had been exercised as of September 30, 2020.

The table below represents a roll-forward of warrant liabilities measured using Level 2 inputs from January 1, 2020 to September 30, 2020 (in thousands):

	Significant Other Observable Inputs (Level 2)
Balance at January 1, 2020	$ 1,485
Change in fair value of warrant liabilities	(469)
Balance at September 30, 2020	$ 1,016

The following table represents a roll-forward of warrants outstanding from January 1, 2020 to September 30, 2020:

	Warrants	Weighted Average Exercise Price
Balance, January 1, 2020	11,921,452	$ 5.97
Exercised	(4,400)	—
Balance, September 30, 2020	11,917,052	$ 5.97

6. Inventories

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

The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's product is subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or the Company identifies excess, obsolete or unsalable inventory, its value is written down to net realizable value. Inventories recorded on the Company's consolidated balance sheets are net of a reserve for expirable inventory of $2.6 million and $3.0 million at September 30, 2020 and December 31, 2019, respectively.

Inventories are comprised of the following (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ —	$ 371
Finished goods, net	28	269
Total inventories, net	**$ 28**	**$ 640**

7. Fixed Assets

Fixed assets consisted of the following (in thousands):

	Useful Lives (Years)	September 30, 2020	December 31, 2019
Leasehold improvements	Shorter of remaining lease term or useful life	$ 10,397	$ 10,397
Office equipment and furniture	3-7	1,363	1,234
Machinery and laboratory equipment	3-7	3,836	3,599
Software	3-5	4,089	3,971
Construction-in-progress	—	—	45
		19,685	19,246
Less accumulated depreciation and amortization		(18,065)	(16,802)
Fixed assets, net		**$ 1,620**	**$ 2,444**

Depreciation and amortization of fixed assets totaled $1.3 million and $1.4 million for the nine months ended September 30, 2020 and 2019, respectively, and $0.5 million for each of the three months ended September 30, 2020 and 2019.

8. Ownership of MeiraGTx Ordinary Shares

The Company maintained a 1.8% and 5.7% ownership in the ordinary shares of MeiraGTx with a fair value of $9.2 million and $42.0 million, at September 30, 2020 and December 31, 2019, respectively. The Company entered into transactions in July 2020 and May 2020 pursuant to which it sold approximately 0.3 million and 1.1 million ordinary shares of MeiraGTx, respectively, for gross proceeds of $4.2 million and $15.5 million, respectively, which was recorded as a realized gain on equity securities during the three and nine months ended September 30, 2020, respectively. The realized gain represents the total gain on the sale of ordinary shares since the MeiraGTx IPO in June 2018. The Company did not realize any gains in the three and nine months ended September 30, 2019. The Company has recorded a net unrealized (loss) gain on its ownership of MeiraGTx ordinary shares of $(3.3) million and $(38.6) million for the three months ended September 30, 2020 and 2019, respectively, and $(32.8) million and $22.3 million for the nine months ended September 30, 2020 and 2019, respectively. The unrealized gains on equity securities consists of two components: (i) the reversal of the gain or loss recognized in previous periods on equity securities sold and (ii) the change in unrealized gain or loss resulting from mark-to-market adjustments on equity securities still held. The Company's ownership of MeiraGTx ordinary shares is valued using Level 1 inputs, which includes quoted prices in active markets for identical assets in accordance with the fair value hierarchy (Note 5).

The table below represents a rollforward of the Company's ownership of MeiraGTx ordinary shares from January 1, 2020 to September 30, 2020 (in thousands):

	Significant Observable Inputs (Level 1)
Balance as of January 1, 2020	$ 41,997
Unrealized loss on ordinary shares sold during the year	(8,244)
Realized gain on sale of ordinary shares	(19,784)
Unrealized loss on remaining ownership of ordinary shares	(4,731)
Balance as of September 30, 2020	$ 9,238

The Company is party to a sublease agreement to provide office space to MeiraGTx, which is automatically renewed on a monthly basis unless MeiraGTx provides 30 days' prior written notice. The Company recognized $0.1 million and $0.4 million to other revenue related to this sublease agreement during each of the three and nine months ended September 30, 2020 and 2019. The Company received cash payments of $0.4 million from MeiraGTx for each of the nine months ended September 30, 2020 and 2019 and had no amounts receivable from MeiraGTx at September 30, 2020 or December 31, 2019.

9. License Agreements

The Company has entered into several license agreements for products currently under development. The Company's license agreements are disclosed in the audited financial statements included in Item 8 of its Annual Report on Form 10-K for the year ended December 31, 2019. Since the date of such financial statements, there have been no significant changes to the Company's license agreements other than described below.

Meiji

In December 2019, the Company entered into a collaboration agreement with Meiji, a Tokyo-based wholly owned subsidiary of Meiji Holdings Co., Ltd., to form a joint venture to exclusively develop and commercialize belumosudil (KD025) in Japan and certain other Asian countries. The joint venture was entered into through the creation of Romeck Pharma, LLC ("Romeck"), whereby the Company entered into a royalty-bearing exclusive license agreement with Romeck and Meiji in exchange for a 50% interest in Romeck. Romeck is domiciled in Japan with shared oversight between the Company and Meiji. Under the terms of the license agreement, the Company received an upfront payment of $6.0 million in January 2020 and is eligible to receive an additional $23.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of belumosudil (KD025) in Japan.

The Company assessed the applicability of ASC 810, *Consolidation*, to the aforementioned agreements and based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, determined that Romeck was a VIE, however consolidation was not required as the Company was not the primary beneficiary based upon the voting and managerial structure of the entity. The purpose of the VIE is to develop and commercialize belumosudil in Japan and the operations of Romeck will be financed entirely by Meiji. The Company has not and is not required to provide financial support under the agreements and has no exposure to loss as a result of its involvement in the VIE. The Company's investment in Romeck was accounted for under the equity method as the Company has the ability to exercise significant influence over Romeck. The equity method investment was recorded at immaterial cost representing the Company's initial capital contribution for its ownership. This value was determined based upon the corporate structure which does not allocate profits or losses to the Company. An adjustment to this recorded investment will only occur upon a sales transaction or liquidation event, as defined in the agreement.

The Company evaluated the arrangement under ASC 808, *Collaborative Arrangements*, and determined that the license agreement and related joint venture with Romeck is not within the scope of ASC 808, and that the license agreement represents a contract with a customer under ASC 606. The Company has determined that the license agreement contains a single combined performance obligation that consists of the exclusive license to Kadmon's intellectual property and related initial technology transfer. All other promises included in the license agreement were deemed to be immaterial in the context of the contract including clinical supply, participation in a JSC, and limited technical assistance as requested by Romeck and Meiji.

The Company determined that the $6.0 million non-refundable, upfront payment under the license agreement constituted the entire consideration to be included in the transaction price at the inception of the arrangement. As such, this amount was allocated to the single performance obligation. The potential development, regulatory and commercial milestone payments and sales-based royalties that the Company is eligible to receive represent variable consideration under the license agreement. The development and regulatory milestone amounts were excluded from the transaction price and were fully constrained based on their probability of achievement and the fact that Company cannot reasonably conclude that a significant reversal of revenue related to these milestones would not occur. Any future sales-based royalties, including commercial milestone payments based on the level of sales, will be included in the transaction price and recognized as revenue when the related sales occur and the milestones are achieved. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The single combined performance obligation represents a license of functional intellectual property. The Company had not received the upfront payment or completed the single combined performance obligation as of December 31, 2019. The Company recognized $6.0 million in license revenue in the first quarter of 2020 upon completion of the initial technology transfer. No other milestone or royalty revenues have been earned as of September 30, 2020.

10. Share-based Compensation

2016 Equity Incentive Plan

A total of 16,194,138 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, 2019. On January 1, 2020, pursuant to the evergreen provision contained in the 2016 Equity Plan, the number of shares reserved for future grants was increased by 5,591,600 shares, which was three and one half percent (3.5%) of the outstanding shares of common stock on December 31, 2019. This reserve will increase each subsequent anniversary through January 1, 2025, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Company's board of directors. At September 30, 2020, there were options to purchase an aggregate of 16,067,285 shares of common stock outstanding at a weighted average price of $5.28 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 $14.0 million and $6.5 million at September 30, 2020 and December 31, 2019, respectively. That expense is expected to be recognized over a weighted average period of 2.1 years and 2.2 years as of September 30, 2020 and December 31, 2019, respectively. The Company recorded share-based compensation expense under the 2016 Equity Plan of $7.1 million and $5.6 million for the nine months ended September 30, 2020 and 2019, respectively, and $2.4 million and $1.5 million for the three months ended September 30, 2020 and 2019

The following table summarizes information about stock options outstanding, not including performance stock options, from January 1, 2020 to September 30, 2020:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance, January 1, 2020	11,802,601	$ 5.59	7.52	$ 9,520
Granted	4,966,040	4.35		
Exercised	(304,669)	3.13		411
Forfeited	(396,687)	4.70		
Balance, September 30, 2020	16,067,285	$ 5.28	7.47	$ 5,322
Options vested and exercisable, September 30, 2020	8,706,640	$ 6.29	6.10	$ 4,105

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value calculated as the difference between the fair value of the Company's common stock at September 30, 2020 ($3.92 per share) and December 31, 2019 ($4.53 per share) and the exercise price, multiplied by the related in-the-money options that would have been received by the option holders had they exercised their options at the end of the fiscal year. This amount changes based on the fair value of the Company's common stock. There were 304,669 options exercised during the nine months ended September 30, 2020 with an aggregate intrinsic value of $0.4 million. There were no options exercised during the nine months ended September 30, 2019.

There were 4,966,040 stock options granted during the nine months ended September 30, 2020 with a weighted-average exercise price of $4.35. During the nine months ended September 30, 2019, 1,593,973 stock options were granted with a weighted-average exercise price of $2.23. 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:

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Weighted average fair value of grants	$2.87	$1.48
Expected volatility	75.46% - 84.95%	76.19% - 77.73%
Risk-free interest rate	0.29% - 1.64%	1.41% - 2.61%
Expected life (years)	5.5 - 6.0	5.5 - 6.0
Expected dividend yield	0%	0%

Performance Options

A total of 1,290,000 Performance Options with an exercise price of $4.06 were outstanding at September 30, 2020 with no intrinsic value and at December 31, 2019 with an intrinsic value of $0.6 million. The weighted average remaining contractual life of outstanding Performance Options at September 30, 2020 was 5.4 years. Compensation expense for Performance Options is recognized on a straight-line basis over the awards' requisite service period. At September 30, 2020, there was $0.1 million of total unrecognized compensation expense related to unvested Performance Options, which is expected to be recognized over a weighted-average period of 0.5 years. At September 30, 2020 and December 31, 2019, 962,502 and 853,335 Performance Options had vested, respectively, and no Performance Options had been exercised.

Stock Appreciation Rights

A total of 835,000 stock appreciation rights ("SARs") with an exercise price of $3.64 were outstanding at both September 30, 2020 and December 31, 2019 with an intrinsic value of $0.2 million and $0.7 million, respectively. The weighted average remaining contractual life of outstanding SARs at September 30, 2020 was 5.8 years. Compensation expense for SARs is recognized on a straight-line basis over the awards' requisite service period. At September 30, 2020, there was $0.1 million of total unrecognized compensation cost related to unvested SARs that is expected to be recognized over a weighted-average period of 0.2 years. At September 30, 2020 and December 31, 2019, 616,667 SARs had vested and no SARs had been exercised.

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

A total of 9,750 units have been granted under the LTIP as of both September 30, 2020 and December 31, 2019. 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, 2020.

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, 2019. The Company's board of directors elected not to increase the shares reserved for issuance under the 2016 ESPP on January 1, 2020. The Company issued 98,840 and 32,273 shares under the 2016 ESPP during the nine months ended September 30, 2020 and 2019, respectively. No meaningful compensation expense was recognized for the ESPP during the three and nine months ended September 30, 2020 and 2019.

11. Accrued Expenses

Short-term accrued expenses at September 30, 2020 and December 31, 2019 include the following (in thousands):

	September 30, 2020	December 31, 2019
Commission payable	$ 1,768	$ 2,395
Compensation, benefits and severance	3,681	4,668
Research and development	3,980	4,962
Other	783	2,223
Total accrued expenses	$ 10,212	$ 14,248

Commission payable

Commission payable represents commissions to third parties for Class E redeemable convertible unit raises during 2014 and 2015. During the three and nine months ended September 30, 2020, the Company recorded $0.6 million as a non-cash gain on extinguishment of obligation due to the expiration of the Company's obligation related to this portion of the commission.

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.

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.

Other

During the three and nine months ended September 30, 2020, the Company recorded $1.0 million as a non-cash gain on extinguishment of obligation due to the expiration of the Company's obligation relating to a terminated license agreement.

12. 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, 2019. Since the date of such financial statements, there have been no material changes to the Company's commitments or contingencies, including leases.

Contingent License Agreement Milestones

The Company has entered into several license agreements for products currently under development (Note 9). The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent milestone payments aggregate to $229.1 million at September 30, 2020. Any payments made prior to FDA approval will be expensed as research and development. Payments made after FDA approval will be capitalized.

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

13. 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, 2019. 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 8).

14. Income Taxes

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

There was no change in deferred tax liability and no income tax expense recorded for the three and nine months ended September 30, 2020 and 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, 2020 and December 31, 2019. At December 31, 2019, the Company had unused federal and state NOL carryforwards of $371.1 million and $307.2 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 $79.9 million of federal NOL carryforwards that will not expire.

In the United States, President Trump signed into law the CARES Act on March 27, 2020, which provides relief to taxpayers affected by COVID-19. The CARES Act includes several business provisions that may impact a company's accounting for income taxes. In addition, the impact of COVID-19 itself on businesses draws attention to certain provisions in ASC 740. The Company analyzed the business provisions in the CARES Act and determined that the Act does not have a significant impact on its income tax provision.

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

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the "Company," "Kadmon," "we," "us" and "our" refer to Kadmon Holdings, Inc. and its consolidated subsidiaries. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Quarterly Report on Form 10-Q and those in included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2019. 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 clinical-stage biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address significant unmet medical needs. Our pipeline includes developmental treatments for immune and fibrotic diseases as well as immuno-oncology therapy candidates. 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 and regulatory events to report in the remainder of 2020 and in 2021.

The Company's most advanced product candidate, belumosudil (KD025) is an orally administered, selective small molecule inhibitor of Rho-associated coiled-coil kinase 2 ("ROCK2"), a signaling pathway that modulates inflammatory response. The Company is initially developing belumosudil for the treatment of chronic graft-versus-host disease ("cGVHD"), an immune-mediated inflammatory and fibrotic disorder. On September 30, 2020, the Company submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for belumosudil for the treatment of patients with cGVHD. The NDA is subject to acceptance by the FDA. The NDA is being reviewed under the Real-Time Oncology Review ("RTOR") pilot program, an initiative of the FDA's Oncology Center of Excellence ("OCE"). The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

The NDA submission is supported by positive data observed in ROCKstar (KD025-213), the Company's pivotal clinical trial evaluating belumosudil in 132 patients with cGVHD who have received two or more prior lines of systemic therapy. As previously reported, belumosudil achieved clinically meaningful and statistically significant Overall Response Rates of 73% with 200 mg once daily and 74% with 200 mg twice daily. Responses were achieved across key patient subgroups and complete responses were observed in all organ systems. Belumosudil has been well tolerated and adverse events have been consistent with those expected in the patient population.

The FDA has granted Orphan Drug Designation to belumosudil for the treatment of cGVHD, and the FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy.

The recent global pandemic caused by a novel strain of the coronavirus SARS-COV-2, which causes a disease that is referred to as coronavirus disease 2019 ("COVID-19"), may materially affect us economically. While the economic impact of the COVID-19 pandemic may be difficult to assess or predict, this widespread pandemic has resulted in a significant disruption of global financial markets, which may reduce our ability to access capital. If the disruption to the financial markets is protracted, our liquidity could be negatively affected in the future. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock. During these uncertain times, the Company's top priorities are to ensure the health and welfare of its employees, maintain product safety and continue to advance its clinical studies. However, our clinical trials have been impacted, and we may experience delays in anticipated timelines and milestones. For instance, due to interruptions at clinical sites, enrollment has been delayed in our ongoing Phase 2 clinical trial of belumosudil in systemic sclerosis and enrollment was also delayed in our ongoing Phase 1 clinical trial of KD033 in patients with metastatic or locally advanced solid tumors. In addition, we may experience disruptions in our supply chain, including our supply of our product candidates, which may adversely affect the conduct of our clinical trials. We rely on contract research organizations ("CROs") to conduct our clinical trials. Our CROs may be unable to conduct clinical trials for product candidates as a result of the COVID-19 pandemic. The COVID-19 pandemic could impact our healthcare systems and our clinical trial sites' ability to conduct trials to varied degrees and times. COVID-

19 creates risk of interrupting availability of necessary clinical supplies as well as local regulatory reviews, hospital ethics committee reviews and site monitors.

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 $415.7 million at September 30, 2020.

Although our commercial business generates revenue through the sale of CLOVIQUE™ (Trientine Hydrocholride), the revenues generated for the three and nine months ended September 30, 2020 and 2019 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.

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, 2019 included in our Annual Report on Form 10-K filed on March 5, 2020 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 ownership of MeiraGTx Holdings plc (“MeiraGTx”) ordinary shares. 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, 2019 included in our Annual Report on Form 10-K filed on March 5, 2020 with the SEC. Since the date of such financial statements, there have been no changes to our significant accounting policies other than those described in Note 2 of the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

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

Results of Operations

Three and Nine Months Ended September 30, 2020 and 2019

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(unaudited) (in thousands)			
Revenues				
Net sales	$ 339	$ 50	$ 1,227	$ 164
Other revenue	151	176	6,446	529
Total revenue	490	226	7,673	693
Cost of sales	214	73	704	149
Write-down of inventory	148	—	1,054	932
Gross profit	128	153	5,915	(388)
Operating expenses:				
Research and development	17,268	13,227	46,658	43,326
Selling, general and administrative	10,865	10,174	30,299	27,101
Total operating expenses	28,133	23,401	76,957	70,427
Loss from operations	(28,005)	(23,248)	(71,042)	(70,815)
Total other income (expense)	3,399	(39,147)	(10,013)	21,172
Income tax expense	—	—	—	—
Net loss	$ (24,606)	$ (62,395)	$ (81,055)	$ (49,643)
Deemed dividend on convertible preferred stock	543	517	1,578	1,540
Net loss attributable to common stockholders	$ (25,149)	$ (62,912)	$ (82,633)	$ (51,183)

Revenues

The increase in total revenue for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 was primarily attributable to a $6.0 million milestone payment earned pursuant to a joint venture and license agreement entered into with Meiji Seika Pharma Co., Ltd (“Meiji”) to develop belumosudil (KD025) in Japan. The increase in net sales for the three and nine months ended September 30, 2020 as compared to the three and nine months ended September 30, 2019 was due to an increase in CLOVIQUE sales.

Cost of sales and write-down of inventory

The increase in cost of sales for the three and nine months ended September 30, 2020 as compared to the three and nine months ended September 30, 2019, was primarily attributable to the increase in CLOVIQUE net sales revenue. The inventory write-downs during the three and nine months ended September 30, 2020 and 2019 related to write-downs of our CLOVIQUE 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 and nine months ended September 30, 2020 as compared to the three and nine months ended September 30, 2019 was primarily related to an increase in development costs for belumosudil.

Selling, general and administrative expenses

The increase in selling, general and administrative expenses for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 was primarily attributable to increased expenses related to the preparation for the potential launch of belumosudil.

Total other income (expense)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(unaudited) (in thousands)		(unaudited) (in thousands)	
Interest income	$ 208	$ 418	$ 802	$ 1,622
Interest expense	(8)	(836)	(13)	(2,516)
Amortization of debt discount	—	(95)	—	(283)
Change in fair value of warrant liabilities	602	(126)	469	(70)
Realized gain on equity securities	4,274	—	19,784	—
Unrealized (loss) gain on equity securities	(3,254)	(38,634)	(32,759)	22,304
Gain on extinguishment of obligation	1,626	—	1,754	—
Other (expense) income	(49)	126	(50)	115
Total other income (expense)	**$ 3,399**	**$ (39,147)**	**$ (10,013)**	**$ 21,172**

The change in other income (expense) for the three and nine months ended September 30, 2020 as compared to other income for the three and nine months ended September 30, 2019 was primarily attributable to the fluctuations in our ownership of MeiraGTx ordinary shares.

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 our 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 our common stock. The stated liquidation preference amount on the 5% convertible preferred stock totaled $34.8 million at September 30, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception through September 30, 2020, we have raised net proceeds from the issuance of equity and debt. We maintained cash, cash equivalents and marketable debt securities of $150.5 million at September 30, 2020. 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,	
	2020	2019
	(unaudited) (in thousands)	
Net cash provided by (used in):		
Operating activities	$ (61,129)	$ (63,947)
Investing activities	(25,168)	(430)
Financing activities	52,650	35,769
Net decrease in cash, cash equivalents and restricted cash	$ (33,647)	$ (28,608)

Operating Activities

The net cash used in operating activities was $61.1 million for the nine months ended September 30, 2020, and consisted primarily of a net loss of $(81.1) million adjusted for $22.8 million in net non-cash items, including unrealized loss on equity securities of $13.0 million, change in fair value of warrant liabilities of $(0.5) million, gain on extinguishment of obligation of $(1.8) million and share-based compensation expense of $7.1 million, offset by the depreciation and amortization of fixed assets and noncash operating lease cost of $3.9 million and write-down of inventory of $1.1 million, as well as a net decrease in operating assets and liabilities of $3.0 million. Once adjusted for the non-cash items above, the cash used in operating activities for the nine months ended September 30, 2020 was primarily driven by selling, general and administrative expenses of $21.5 million and research and development expense of $44.5 million related to the advancement of our clinical product candidates.

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.

Investing Activities

Net cash used in investing activities was $25.2 million for the nine months ended September 30, 2020, consisting primarily of purchases of investment debt securities of $44.6 million, offset by proceeds from the sale of a portion of our investment in MeiraGTx of $19.8 million. 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, MA and the purchase of laboratory equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 was $52.7 million, consisting primarily of net proceeds from the issuance of common stock in our ATM Offering of $48.5 million. 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 through the ATM Offering of $35.7 million.

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, seek regulatory approvals for our product candidates and advance our planned commercial launch efforts for belumosudil, if approved. 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, 2020 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. Our funding requirements may be affected by the COVID-19 pandemic to the extent timelines for clinical trials and product approvals may be extended and access to capital may be reduced. As a result, our management will retain broad discretion over the allocation of our existing cash, cash equivalents, and marketable debt securities. In addition, we anticipate the need to raise additional funds from the issuance of additional debt or equity securities and monetization of assets, and our management will retain broad discretion over the allocation of those funds.

Contractual Obligations and Commitments

There have been no material changes in our contractual obligations and commitments during the nine months ended September 30, 2020 from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2019 and those disclosed in Note 12 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, 2020, 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, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) occurred during the fiscal quarter ended September 30, 2020 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

Although not required to provide the information required by this Item, the Company is supplementing and updating the risk factors in its prior filings with the SEC, including those discussed under the heading "Item 1A. Risk Factors," in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 5, 2020, with the following:

Our business could be adversely affected by the effects of health epidemics and pandemics, including the recent COVID-19 pandemic, in regions where we or third parties on which we rely have significant concentrations of clinical trial sites or other business operations. The COVID-19 pandemic has impacted our operations, including at our corporate headquarters in New York, commercial operations in Pennsylvania, clinical operations in Massachusetts, research facility in New Jersey and at our clinical trial sites, as well as the business or operations of our CROs or other third parties with whom we conduct business. If these impacts continue for an extended period of time, our business could be materially and adversely affected.

Our business could be adversely affected by health epidemics in regions where we have clinical trial sites or other business operations and could cause significant disruption in the operations of CROs upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and several European countries. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Further, the President of the United States declared the COVID-19 pandemic a national emergency. The Governors of New York, Pennsylvania, New Jersey and Massachusetts declared a state of emergency related to the spread of COVID-19, and issued orders directing all individuals, including where our headquarters is located, to "stay at home" except to perform certain essential activities. The orders took effect in March 2020. We have temporarily implemented work-from-home policies for all employees. The impacts of the state orders and our work-from-home policies have impacted productivity in certain business units, impacted management attention, depleted resources, disrupted our business and delayed our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar disruptions in our operations could materially and adversely impact our business, operating results and financial condition. In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. For instance, due to interruptions at clinical sites, enrollment has been delayed in our ongoing Phase 2 clinical trial of belumosudil (KD025) in systemic sclerosis and enrollment was also delayed in our ongoing Phase 1 clinical trial of KD033 in patients with metastatic or locally advanced solid tumors. Also, some patients may not be able to comply with clinical trial protocols if quarantine impedes patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. The COVID-19 pandemic may materially affect us economically. While the economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, potentially reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The impacts of the COVID-19 pandemic may also exacerbate other risks discussed in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2019, any of which could have a material effect on us. This situation is changing rapidly and additional impacts may arise that we are not aware of currently.

Our business could be adversely affected by the cyber, privacy and productivity effects of remote working and disruption at management and board levels due to COVID-19.

We have transitioned all of our employee population to a remote work environment in an effort to mitigate the spread of COVID-19, which may exacerbate certain risks to our business, including an increased demand for information technology resources, increased risk of phishing and other cybersecurity attacks, and increased risk of unauthorized dissemination of sensitive personal information or proprietary or confidential information about us or our members or other third-parties. We may experience disruptions to our business operations resulting from quarantines, self-isolations, or other movement and restrictions on the ability of our employees to perform their jobs that may impact our ability to progress our clinical candidates in a timely manner or meet development milestones. The COVID-19 pandemic could also disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of

management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. COVID-19 illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

We may not be entitled to forgiveness of our recently received Loan under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could damage our reputation.

On April 14, 2020 we received proceeds of $3.1 million from a loan under the Paycheck Protection Program ("PPP Loan") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which we intend to use to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 15, 2022 and bears interest at a rate of 1% per annum. On August 20, 2020, the loan was amended so that, commencing August 15, 2021, the Company is required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 15, 2022 the principal amount outstanding on the PPP Loan as of October 15, 2020. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest. While we have begun preparations to apply for forgiveness, we cannot provide any assurance that we will be eligible for loan forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the U.S. Small Business Administration ("SBA"). Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan. In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our entire workforce, notwithstanding certain obvious "work-from-home" limitations associated with the nature of our business and managing risks to our development programs. In considering our position, the Company, an emerging growth clinical-stage biopharmaceutical research and development company with approximately 120 employees (including 27 research staff ordinarily located within the Company's laboratories), currently conducting 6 clinical trials to develop at least 3 medicines for currently unmet and under-served medical needs, took into account our classification as a smaller reporting Company under SEC rules, our ability to currently access alternative forms of capital in the current market environment, and that management expressed substantial doubt as described in Note 1 of the financial statements in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2020 about our ability to continue as a going concern based upon our recurring and continuing losses from operations and our need for additional funding to continue operations. The report of our independent registered public accounting firm BDO USA, LLP also included an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP of the CARES Act, and following receipt of the loan, we have made no COVID-19 layoffs. The certification described above did not contain any objective criteria and is subject to interpretation. We will continue to assess our continued qualification if and when updated guidance is released by the Treasury Department. If, despite our good-faith belief that given our circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any applicable laws or regulations or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties, which could also result in adverse publicity and damage to reputation. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. If these events were to transpire, they could have a material adverse effect on our business, results of operations and financial condition.

Review of our NDA for belumosudil under the FDA's RTOR pilot program may not lead to a faster regulatory review or approval, and do not increase the likelihood that belumosudil will obtain marketing approval.

The FDA or other regulatory bodies periodically introduce pilot programs with the goal of a more efficient review of applications, including the FDA OCE's RTOR pilot program, which is currently being tested by the FDA. The RTOR pilot program allows the FDA to review data before the applicant formally submits its completed application, aiming to explore a more efficient review process.

In September 2020, we submitted a NDA to the FDA for belumosudil for the treatment of patients with chronic graft-versus-host disease (cGVHD) after failure of two or more lines of systemic therapy. The NDA remains subject to acceptance by the FDA. Acceptance by the FDA marks the commencement of the FDA's formal review process, and the initiation of the regulatory deadlines under the Prescription Drug User Fee Act. The NDA is being reviewed under the RTOR pilot program.

Although the RTOR pilot program and other designations we may receive or programs we may participate in, are intended to expedite the review and approval of product candidates, they do not ensure that marketing approval will be granted in a particular timeframe, or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant designations for expedited review or include product candidates within various programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even if we or our partners receive such designations or our product candidates are eligible for inclusion in expedited review programs in the future, we may not experience a faster development, review, or approval process compared to conventional procedures. Furthermore, these designations and programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted priority review or other expedited review designations or subject to these various programs may be denied based on study data, study design, or other factors.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	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).
3.2	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).
3.3	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).
31.1*	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.
31.2*	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.
32.1**	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.
32.2**	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.
101.INS*	Inline XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101)

*Filed herewith.

**Furnished herewith. In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

Date: November 5, 2020 By: /s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2020 By: /s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: November 5, 2020 By: /s/ Kyle Carver
Kyle Carver
Principal Accounting Officer, Controller
(Principal Accounting Officer)

EXHIBIT 31.1

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 5, 2020

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

EXHIBIT 31.2

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 5, 2020

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Kadmon Holdings, Inc. (the "Company") for the period ended September 30, 2020 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 5, 2020

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

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Kadmon Holdings, Inc. (the "Company") for the period ended September 30, 2020 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 5, 2020

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