Kadmon Highlights Recent Progress and Reports Fourth Quarter and Full Year 2019 Financial Results

March 5, 2020

NEW YORK, March 05, 2020 (GLOBE NEWSWIRE) -- Kadmon Holdings, Inc. (NYSE: KDMN) today provided a business update and reported financial and operational results for the fourth quarter and full year ended December 31, 2019.

“We achieved significant progress in 2019, led by positive results from the interim analysis of the pivotal trial of KD025 in cGVHD that greatly exceeded the threshold for success, achieving overall response rates of 64% and 67% with KD025 200 mg QD and 200 mg BID, respectively; we also recently presented detailed efficacy and safety data from this trial, further underscoring the therapeutic potential of KD025 in this indication,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “We will meet with the FDA later this month to discuss our planned NDA submission of KD025 and expect to provide an update of that meeting, along with topline results from the primary analysis of the pivotal trial, in the second quarter of 2020. Finally, we raised approximately $123 million and fully paid off our term debt in the fourth quarter of 2019, strengthening our financial position and ability to execute on our anticipated milestones.”

2020 Anticipated Key Clinical Milestones:

KD025

- Hold pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in March 2020 to discuss regulatory pathway for KD025 in chronic graft-versus-host disease (cGVHD); provide an update on the meeting in the second quarter of 2020
- Announce topline results from primary analysis of pivotal trial in cGVHD (KD025-213) in the second quarter of 2020
- Complete enrollment in ongoing Phase 2 clinical trial in systemic sclerosis (KD025-209)

KD033

- Initiate clinical trial of KD033, Kadmon’s anti-PD-L1/IL-15 fusion protein for the treatment of solid tumors, in the second quarter of 2020

KD045

- Continue ongoing Investigational New Drug Application (IND)-enabling activities of KD045, Kadmon’s next-generation ROCK inhibitor for the treatment of fibrotic diseases

Q4 2019 Key Business Highlights:

- Closed underwritten public offering of 29.9 million shares of common stock for gross proceeds of $101.6 million, including full exercise of the underwriters’ option to purchase additional shares
- Divested 1.4 million ordinary shares of MeiraGTx Holdings plc (MGTX), bringing $22 million in net proceeds
- Paid off term debt in full; the Company no longer maintains any term debt obligations
- Established strategic partnerships to develop KD025 in China and Japan with BioNova Pharmaceuticals Ltd. (BioNova) and Meiji Seika Pharma Co., Ltd., respectively

Financial Results

Fourth Quarter 2019 Results

Loss from operations for the three months ended December 31, 2019 was $18.3 million, compared to $27.8 million for the same period in 2018.

The decrease in loss from operations was primarily due to $4.0 million of license revenue recognized by the Company during the three months ended December 31, 2019 related to the BioNova strategic partnership. The decrease was also driven by a decrease in research and development expense due to timing of direct external costs associated with development of KD025 and compensation for research and development personnel.

Full Year 2019 Results

Loss from operations for the year ended December 31, 2019 was $89.1 million, compared to $85.9 million for the same period in 2018.

The increase in loss from operations was primarily due to an increase in research and development expenses for the year ended December 31, 2019 of $7.5 million, offset by $4.0 million of revenue associated with the BioNova strategic partnership. The increase in research and development expenses was primarily related to direct external costs of KD025 development.

Liquidity and Capital Resources

At December 31, 2019, the Company's cash and cash equivalents totaled $139.6 million, compared to $94.7 million at December 31, 2018. In addition, as of December 31, 2019, the Company held approximately 2.1 million ordinary shares of MGTX, a publicly traded, clinical-stage gene therapy company.

About KD025

KD025 is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates immune response as well as fibrotic pathways. In addition to the pivotal trial in cGVHD, KD025 is being studied in an ongoing Phase 2 clinical trial in adults with diffuse cutaneous systemic sclerosis (KD025-209). The FDA has granted Breakthrough Therapy Designation to KD025 for the treatment of patients with cGVHD after failure of two or more prior lines of systemic therapy. The FDA has also granted Orphan Drug Designation to KD025 for the treatment of patients with cGVHD.

About Kadmon

Kadmon is a clinical-stage biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. Our clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies.

Forward Looking Statements

This press release contains forward-looking statements. Such statements may be preceded by the words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, (i) the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; (ii) our ability to advance product candidates into, and successfully complete, clinical trials; (iii) our reliance on the success of our product candidates; (iv) the timing or likelihood of regulatory filings and approvals; (v) our ability to expand our sales and marketing capabilities; (vi) the commercialization of our product candidates, if approved; (vii) the pricing and reimbursement of our product candidates, if approved; (viii) the implementation of our business model, strategic plans for our business, product candidates and technology; (ix) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (x) our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; (xi) costs associated with defending intellectual property infringement, product liability and other claims; (xii) regulatory developments in the United States, Europe, China, Japan and other jurisdictions; (xiii) estimates of our expenses, future revenues, capital requirements and our needs for additional financing; (xiv) the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; (xv) our ability to maintain and establish collaborations or obtain additional grant funding; (xvi) the rate and degree of market acceptance of our product candidates; (xvii) developments relating to our competitors and our industry, including competing therapies; (xviii) our ability to effectively manage our anticipated growth; (xix) our ability to attract and retain qualified employees and key personnel; (xx) the use of proceeds from our recent public offerings; (xxi) the potential benefits of any of our product candidates being granted orphan drug designation; (xxii) the future trading price of the shares of our common stock and impact of securities analysts' reports on these prices; (xxiii) our intentions with respect to our holdings of shares of MeiraGTx; and/or (xxiv) other risks and uncertainties. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including Kadmon's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Kadmon Holdings, Inc.
Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			
Revenues				
Net sales	$ 256	$ 58	$ 420	$ 691
License and other revenue	4,146	174	4,675	705
Total revenue	4,402	232	5,095	1,396
Cost of sales	228	51	377	412
Write-down of inventory	(20)	5	912	270
Gross profit	4,194	176	3,806	714
Operating expenses:				
Research and development	13,135	17,090	56,461	48,966
Selling, general and administrative	9,324	10,914	36,425	37,644
Total operating expenses	22,459	28,004	92,886	86,610
Loss from operations	(18,265)	(27,828)	(89,080)	(85,896)
Total other income (expense)	6,586	(13,651)	27,758	31,120

Income tax expense (benefit)	46	38	46	(524)
Net loss	$ (11,725)	$ (41,517)	$ (61,368)	$ (54,252)
Deemed dividend on convertible preferred stock	518	515	2,058	2,011
Net loss attributable to common stockholders	$ (12,243)	$ (42,032)	$ (63,426)	$ (56,263)
Basic and diluted net loss per share of common stock	$ (0.09)	$ (0.37)	$ (0.48)	$ (0.58)
Weighted average basic and diluted shares of common stock outstanding	144,023,602	113,130,817	132,308,548	97,609,000

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

	December 31,	
	2019	**2018**
Cash and cash equivalents	$ 139,597	$ 94,740
Other current assets	3,010	4,196
Investment, equity securities – current	41,997	—
Investment, equity securities – noncurrent	—	34,075
Other noncurrent assets	30,194	11,650
Total assets	$ 214,798	$ 144,661
Current liabilities	28,742	24,018
Other long term liabilities	20,321	4,752
Secured term debt – net of current portion and discount	—	27,480
Total liabilities	49,063	56,250
Total stockholders' equity	165,735	88,411
Total liabilities and stockholders' equity	$ 214,798	$ 144,661

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