



August 9, 2012

Medivation Reports Second Quarter Financial Results and Provides Corporate Update

Conference Call Today at 4:30 p.m. Eastern Time

SAN FRANCISCO, CA -- (Marketwire) -- 08/09/12 -- Medivation, Inc. (NASDAQ: MDVN) today provided a corporate update and reported its financial results for the second quarter ended June 30, 2012.

"The FDA's recent decision to grant enzalutamide priority review sets the stage for the potential approval and launch of enzalutamide this year for the treatment of men with castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy. Our highest priority is to work with the FDA to bring a potentially important treatment option to physicians and patients in this area of significant unmet medical need," said David Hung, M.D., president and chief executive officer of Medivation. "With our partner Astellas, we continue to investigate the potential benefits and risks of enzalutamide through a robust clinical development program."

Recent Developments and Anticipated Milestones

Enzalutamide (formerly MDV3100)

- The U.S. Food and Drug Administration (FDA) accepted for filing the New Drug Application (NDA) for enzalutamide for the potential treatment of men with castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy and granted priority review designation. The Prescription Drug User Fee Act (PDUFA) date for the completion of the FDA's review of the NDA is November 22, 2012. The FDA's acceptance for filing of the NDA triggers a \$10 million milestone payment to Medivation during the third quarter under its collaboration agreement with Astellas.
- Submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for enzalutamide for the treatment of adult men with metastatic castration-resistant prostate cancer who have received docetaxel therapy.
- Presented data at the 2012 American Society of Clinical Oncology Annual Meeting from the Phase 3 AFFIRM trial showing enzalutamide's benefits on the secondary endpoints of health-related quality of life and time to first skeletal-related event in men with castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy.
- Completed recruitment of its sales and medical affairs field forces in preparation for the potential launch of enzalutamide in the U.S. this year. Medivation will provide fifty percent of the sales and medical affairs field forces in support of enzalutamide in the U.S. should it receive marketing approval.

Enzalutamide Clinical Development Program

- Completed targeted enrollment of 1,680 patients in the Phase 3 PREVAIL trial of enzalutamide in men with castration-resistant prostate cancer who have not yet received chemotherapy. The co-primary endpoints in this trial are overall survival and progression-free survival.
- Expanded its development program comparing enzalutamide's effects on progression-free-survival when compared head-to-head versus bicalutamide, the most commonly used anti-androgen, in men who have progressed following medical castration with LHRH analog therapy or surgical castration.
 - Continued to enroll patients in the TERRAIN trial, which is enrolling approximately 370 men with metastatic disease primarily in Europe; and
 - Initiated patient enrollment in the STRIVE trial, which is enrolling approximately 400 men with either metastatic or non-metastatic disease primarily in the U.S.
- Completed patient enrollment in an open-label clinical trial designed to evaluate the effect of enzalutamide in 67 men with advanced prostate cancer who have not had any previous hormonal therapies. The primary endpoint in this trial is prostate specific antigen response.
- Study sites are being initiated in the ASPIRE trial, an open-label study evaluating enzalutamide in approximately 150 men with castration-resistant prostate cancer who are eligible to receive chemotherapy but have elected not to do so. The

primary endpoint in this trial is radiographic progression-free survival.

- Began patient enrollment in an open-label clinical trial evaluating enzalutamide as neoadjuvant therapy in approximately 50 men prior to prostatectomy. The primary endpoint in this trial is pathological complete response rate.
- Continued to enroll patients in an open-label study evaluating the safety, tolerability and pharmacokinetics of enzalutamide when dosed in combination with docetaxel in 18 men with castration-resistant prostate cancer.
- Initiated patient enrollment in an open-label Phase 1 study in approximately 24 patients with breast cancer. The study is designed to evaluate the safety and tolerability of enzalutamide in breast cancer patients who have failed prior hormonal therapy.

Second Quarter 2012 Financial Results

Revenue for the second quarter of 2012 was \$42.9 million, consisting of partial recognition of the non-refundable up-front and development milestone payments to date from the Company's corporate partner Astellas and former partner Pfizer. These payments were recorded as deferred revenue upon receipt and are being recognized as revenue on a straight-line basis over the estimated performance period of the Company's obligations under the applicable collaboration agreement.

Due to the termination of the Pfizer collaboration, the Company recognized \$35.6 million of deferred revenue from that collaboration in the second quarter of 2012 and expects to recognize the remaining \$5.5 million of deferred revenue from that collaboration in the third quarter of 2012. Based on its current estimate of the performance period under the Astellas collaboration, the Company expects to recognize the \$58.0 million of deferred revenue remaining from that collaboration as of June 30, 2012 at a rate of approximately \$7.3 million per quarter until all such deferred revenue has been recognized.

Total operating expenses for the second quarter were \$43.9 million, compared with total operating expenses of \$26.2 million for the same period in 2011. These figures include non-cash stock-based compensation expense of \$5.6 million in the quarter ended June 30, 2012, compared with \$3.7 million for the same period in 2011.

Medivation reported a net loss for the quarter ended June 30, 2012 of \$5.5 million, or \$0.15 per diluted share, compared with a net loss of \$9.5 million, or \$0.27 per diluted share, for the same period in 2011.

Cash, cash equivalents and short-term investments at June 30, 2012 totaled \$344.5 million, compared with \$380.1 million at March 31, 2012.

2012 Financial Outlook

Medivation expects total operating expenses for 2012, net of cost-sharing payments from Astellas, to be between \$183 and \$198 million, approximately \$25 million of which consists of non-cash stock-based compensation expense. This increase from prior guidance of between \$155 and \$170 million is due primarily to increased U.S. commercial launch-related costs of \$19 million and increased non-cash stock-based compensation costs of \$8 million. Medivation continues to expect to incur approximately \$15 million in capital expenditures in 2012, primarily related to leasehold improvements at its new corporate and commercial headquarters facilities.

Medivation became entitled to receive a \$10 million milestone payment from Astellas upon the FDA's acceptance for filing of the enzalutamide NDA in July 2012. Medivation expects to become entitled to receive an additional \$35 million in development milestone payments from Astellas in 2012, based on the assumed acceptance for filing of the MAA in Europe (\$5 million) and the anticipated approval of the U.S. NDA (\$30 million). Medivation is required to share ten percent of all development milestone payments received with the licensor of its enzalutamide technology.

Conference Call Information

To participate by telephone in today's live call beginning at 4:30 p.m. Eastern Time, please call 877-303-2523 from the U.S. or +1-253-237-1755 internationally.

About Medivation

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel therapies to treat serious diseases for which there are limited treatment options. Medivation aims to transform the treatment of these diseases and offer hope to critically ill patients and their families. For more information, please visit us at www.medivation.com.

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding: the continued clinical development of Medivation's product candidates and potential future progress related thereto; the therapeutic potential of Medivation's product candidates; patient screening for and enrollment in ongoing and new clinical trials; potential future regulatory approval of enzalutamide and the timing thereof;

the continued effectiveness of, and continuing collaborative activities and benefits under, Medivation's collaboration agreement with Astellas; and anticipated future financial results, including revenue recognition, operating expenses, capital expenditures and receipt of development milestone payments under Medivation's collaboration agreement with Astellas. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those projected, including, without limitation, risks related to the potential regulatory approval and commercialization of enzalutamide and related timing, progress and results of Medivation's clinical trials, including the risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of some or all of Medivation's product development activities, the risk that positive results seen in our clinical trials may not be predictive of the results of our ongoing or planned clinical trials and the risk that life-prolonging treatments could prevent ongoing or planned enzalutamide trials from succeeding or could reduce any potential survival benefit that may be shown in these trials even if they do succeed, difficulties or delays in enrolling and retaining patients in Medivation's clinical trials, including as a result of the availability of competing treatments or clinical trials of competing drugs for the same indication, Medivation's dependence on the efforts of and funding by Astellas for the development of enzalutamide, the achievement of development, regulatory and commercial milestones under Medivation's collaboration agreement, the manufacturing of Medivation's product candidates, the industry and competitive market, the adequacy of Medivation's financial resources, unanticipated expenditures or liabilities, Medivation's outstanding convertible senior notes, intellectual property matters, and other risks detailed in Medivation's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended June 30, 2012, filed today with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Medivation disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

MEDIVATION, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|-----------|------------------|-----------|
| | June 30, | | June 30, | |
| | 2012 | 2011 | 2012 | 2011 |
| Collaboration revenue | \$ 42,912 | \$ 15,799 | \$ 79,737 | \$ 30,508 |
| Operating expenses: | | | | |
| Research and development | 21,550 | 19,139 | 41,580 | 36,757 |
| Selling, general and administrative | 22,337 | 7,036 | 38,024 | 13,192 |

| | | | | |
|---|------------|------------|------------|-------------|
| Total operating expenses | 43,887 | 26,175 | 79,604 | 49,949 |
| | ----- | ----- | ----- | ----- |
| Income (loss) from operations | (975) | (10,376) | 133 | (19,441) |
| Other income (expense): | | | | |
| Interest expense | (4,688) | -- | (5,273) | -- |
| Interest income | 56 | 9 | 83 | 50 |
| Other income (expense) | 83 | (99) | (15) | (432) |
| | ----- | ----- | ----- | ----- |
| Total other income (expense), net | (4,549) | (90) | (5,205) | (382) |
| | ----- | ----- | ----- | ----- |
| Net loss before income tax benefit | (5,524) | (10,466) | (5,072) | (19,823) |
| Income tax benefit | (24) | (992) | (12) | (1,897) |
| | ----- | ----- | ----- | ----- |
| Net loss | \$ (5,500) | \$ (9,474) | \$ (5,060) | \$ (17,926) |
| | ===== | ===== | ===== | ===== |
| Basic and diluted net loss per common share | \$ (0.15) | \$ (0.27) | \$ (0.14) | \$ (0.52) |
| | ===== | ===== | ===== | ===== |
| Weighted average common shares used in the calculation of basic and diluted net loss per common share | 36,385 | 34,888 | 36,169 | 34,776 |
| | ===== | ===== | ===== | ===== |

MEDIVATION, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

(unaudited)

| | June 30, 2012 | December 31, 2011 |
|---|------------------|----------------------|
| | ----- | ----- |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 144,519 | \$ 70,136 |
| Short-term investments | 199,948 | 74,996 |
| Receivables from collaboration partners | 14,501 | 12,545 |
| Prepaid expenses and other current assets | 13,491 | 10,512 |
| | ----- | ----- |
| Total current assets | 372,459 | 168,189 |
| Property and equipment, net | 12,525 | 720 |
| Restricted cash | 6,305 | 5,489 |
| Other non-current assets | 5,397 | 719 |
| | ----- | ----- |
| Total assets | \$ 396,686 | \$ 175,117 |
| | ===== | ===== |

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

| | | |
|------------------|-----------|----------|
| Accounts payable | \$ 10,016 | \$ 5,588 |
| Accrued expenses | 46,868 | 24,014 |
| Deferred revenue | 34,510 | 59,762 |

| | | |
|--|------------|------------|
| Other current liabilities | 189 | 270 |
| | ----- | ----- |
| Total current liabilities | 91,583 | 89,634 |
| Convertible notes, net of unamortized discount of \$68,567 at June 30, 2012 | 190,183 | -- |
| Deferred revenue, net of current | 29,024 | 83,509 |
| Other non-current liabilities | 2,515 | 653 |
| | ----- | ----- |
| Total liabilities | 313,305 | 173,796 |
| | ----- | ----- |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.01 par value per share; 1,000,000 shares authorized; no shares issued and outstanding | -- | -- |
| Common stock, \$0.01 par value per share; 50,000,000 shares authorized; 36,681,369 and 35,731,838 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively | 367 | 357 |
| Additional paid-in capital | 338,362 | 251,242 |
| Accumulated other comprehensive gain | 3 | 13 |
| Accumulated deficit | (255,351) | (250,291) |
| | ----- | ----- |
| Total stockholders' equity | 83,381 | 1,321 |
| | ----- | ----- |
| Total liabilities and stockholders' equity | \$ 396,686 | \$ 175,117 |
| | ===== | ===== |

Contacts:

Patrick Machado

Chief Business & Financial Officer

(415) 829-4101

Anne Bowdidge

Sr. Director, Investor Relations

(650) 218-6900

Source: Medivation

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