15 April 2016

Medivation (MDVN)

Potential Deal

We would be long MDVN common or long June 55 Calls.

Potential sale of the co.: Bloomberg said, citing sources, that MDVN rebuffed a recent takeover approach from SNY, which is pursuing the U.S. company to expand its cancer treatment business. Sanofi is working with advisers on a potential offer and hasn't ruled out making a hostile bid. Medivation hired defense advisers after it received preliminary interest from potential buyers. MDVN is seeking a higher price than initial proposals have indicated. Other suitors are also considering making an offer.

IGR view: We believe that the risk-reward for a position long MDVN (or alternatively June 55 Calls) is attractive.

- MDVN's standalone value is likely to have been rerated. Assuming 7.0x FY2016E EV/Sales, we estimate MDVN standalone value at $40 per share.
  - The next key catalysts for MDVN come in 2H/2016.
- We estimate that MDVN may fetch as much as $75 per MDVN share through a bidding process.
- We believe that MDVN is a unique asset offering significant upside potential through expansion of label for its marketed product, XTANDI (in addition to further growth potential from increasing penetration) and its pipeline.
- There appear to be several bidders for the company, and a bidding war for a strategic asset makes the upside potential even more attractive.
  - Standstill with Astellas expires in September 2016.
- We also note that apart from a poison pill, MDVN does not appear to have any other takeover defenses.
- Management appears to be incentivized to maximize shareholder value.

Valuation: By our ROIC calculations and targeting WACC of 8.0%, we estimate that in a competitive bidding situation, MDVN may fetch as much as $75 per share.

- We note that our ROIC analysis does not attach much value to XTANDI's expansion potential and to MDVN's pipeline. We also assumed no tax savings for a foreign buyer.
- We did assume annual cost savings of $240m (approximately 28% of forecast FY2021E operating costs of MDVN).

Strategic drivers: We believe that there are three drivers for the deal: i) potential to increased penetration for XTANDI; ii) potential for indication expansion; and iii) promising oncology pipeline.

Xtandi currently has fairly low penetration of its addressable prostate cancer population, although we also note that revenue growth has slowed down earlier than expected. It is expected that TERRAIN and STRIVE approval will increase penetration for XTANDI. .

- Currently, XTANDI is expected to generate $2bn peak revenue, however, this could be expanded through indication expansion and increase in penetration. It has been argued that XTANDI's revenue opportunity could be in the $6bn to $8bn range.
- Multiple Phase 2 and 3 trials underway to expand the indication of Xtandi to other forms of cancer
- The two key pipeline assets are MDV3800 and MDV9300.
  - MDV3800 was highlighted as a potential best in class PARP inhibitor.
  - Peak U.S. revenue for talazoparib could be between $800m to $2.0bn depending on indication expansion and efficacy.
- We note that analysts have not really attached much value to XTANDI label expansion and the MDVN pipeline.

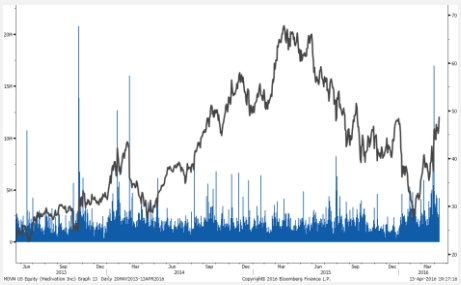
Offer Terms

n.a.

Target: Medivation, Inc.

Country	United States
Bloomberg	MDVN
Sector	Biotechnology
Share price ($)	49.22
Market cap ($)	8,084
Free float (%)	~100

MDVN Price Chart



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Key terms of the merger

Transaction Details	
Announcement Date	N.A.
Offer structure	N.A.
Target's Board Recommendation	N.A.
Target Incorporation	Delaware
By-laws	Click here for the by-laws.
Certificate of inc.	Click here for the charter.

Dividends

MDVN doesn't pay any dividends.

Capital Structure

- **MDVN equity** — There were 164,233,527 MDVN common shares outstanding as of February 16, 2016.
- **MDVN debt** — At December 31, 2015, MDVN had $75.0 million outstanding under the co.'s Revolving Credit Facility and approximately $54.9 million of minimum lease commitments.
- **MDVN Credit rating** — N.A.

MDVN Equity Incentive Plan: Change of Control

The Medivation Equity Incentive Plan, which is stockholder-approved, provides for the issuance of options and other stock-based awards, including restricted stock units and stock appreciation rights. The vesting of all outstanding awards under the Medivation Equity Incentive Plan will accelerate, and all such awards will become immediately exercisable, upon a "change of control" of Medivation, as defined in the Medivation Equity Incentive Plan.

- As of December 31, 2015, approximately **10.1m stock options were outstanding (7m vested and exercisable).**
- As of December 31, 2015, approximately **8.7 million shares were available for issuance** under the Medivation Equity Incentive Plan.

MDVN takeover defenses

- **MDVN Incorporation** — **Delaware**
- **Astellas collaboration**
  - MDVN has a collaboration agreement with Astellas, pursuant to which MDVN is collaborating to develop and commercialize XTANDI globally for all indications, dosages, and formulations of enzalutamide.
    - The companies licensed the intellectual property rights covering XTANDI from the Regents of the University of California, or UCLA or Regents, pursuant to a license agreement.
  - In the United States, decisions are generally made by consensus, pre-tax profits and losses are shared equally, and, subject to certain exceptions, development and commercialization costs are also shared equally.
  - Outside the United States, decisions are generally made by Astellas and all development and commercialization costs are borne by Astellas.
    - Astellas retains all ex-U.S. profits and losses, and pays MDVN a tiered royalty ranging from the low teens to the low twenties as a percentage of aggregate net sales of XTANDI outside the United States, or ex-U.S. XTANDI net sales.
  - The Astellas Collaboration Agreement further provides for a standstill period during which Astellas, as defined in the Astellas Collaboration Agreement, agreed to certain restrictive covenants, including that they would not, directly or indirectly (subject to certain exceptions), unless invited to do so by MDVN, acquire (a) all or substantially all of MDVN's consolidated assets or (b) beneficial ownership of more than 5% of any voting securities of MDVN or any subsidiary or Affiliate of MDVN.
    - The **standstill** period will expire in **September 2016**.
- **Poison Pill** — **Yes.**
  - The rights are exercisable only if a person or group acquires 20% or more of MDVN's common stock or announces a tender or exchange offer which would result in ownership of 20% or more of MDVN's common stock.
  - Following the acquisition of 20% or more of MDVN's common stock, the holders of the rights, other than the acquiring person or group, may purchase MDVN common stock at half of its fair market value.

	○ In the event of a merger or other acquisition of MDVN, the holders of the rights, other than the acquiring person or group, may purchase shares of the acquiring entity at half of their fair market value.
■ **Staggered Board**	■ **No.**
■ **Number of directors**	■ **Charter:** The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the Bylaws. ○ The phrase "whole Board" and the phrase "total number of directors" shall be deemed to have the same meaning, to wit, the total number of directors which the Corporation would have if there were no vacancies. ○ No election of directors need be by written ballot. ■ **Bylaws:** The number of directors which shall constitute the whole board shall be fixed by resolution of the Board from time to time, but so long as the corporation has at least three stockholders, the number of directors shall be at least three.
■ **Removal of directors**	■ **Bylaws:** During such time or times that the corporation is subject to Section 2115(b) of the CGCL, the Board of Directors or any individual director may be removed from office at any time **without cause by the affirmative vote of the holders of at least a majority of the outstanding shares entitled to vote on such removal**; provided, however, that unless the entire Board is removed, no individual director may be removed when the votes cast against such director's removal, or not consenting in writing to such removal, would be sufficient to elect that director if voted cumulatively at an election which the same total number of votes were cast (or, if such action is taken by written consent, all shares entitled to vote were voted) and the entire number of directors authorized at the time of such director's most recent election were then being elected.
■ **Shareholders' right to call special meetings**	■ **Yes.** ○ At any time or times that the corporation is subject to Section 2115(b) of the California General Corporation Law ("CGCL"), stockholders holding **five percent (5%) or more of the outstanding shares shall have the right to call a special meeting of stockholders** only as set forth in Section 17(b) herein. If a special meeting is properly called by such stockholders, the request shall be in writing, specifying the general nature of the business proposed to be transacted, and shall be delivered personally or sent by certified or registered mail, return receipt requested, to the Secretary of the corporation.
■ **Amendment to the bylaws**	■ **Bylaws:** Subject to the limitations set forth in Section 42(h) of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the corporation. The stockholders also shall have power to adopt, amend or repeal the Bylaws of the corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the corporation required by law or by the Certificate of Incorporation, such action by stockholders shall require **the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of the capital stock of the corporation** entitled to vote generally in the election of directors, voting together as a single class.
■ **Amendment to Charter**	■ **Charter:** From time to time any of the provisions of this certificate of incorporation may be amended, altered, or repealed, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted in the manner and at the time prescribed by said laws, and all rights at any time conferred upon the stockholders of the Corporation by this certificate of incorporation are granted subject to the provisions of this Article.
■ **Actions by written consent**	■ **Yes.** ○ **Bylaws:** In order that the corporation may determine the stockholders entitled to consent to corporate action in writing without a meeting (including by telegram, cablegram or other electronic transmission as permitted by law), the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which date shall not be more than ten (10) days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. Any stockholder of record seeking to have the stockholders authorize or take corporate action by consent shall, by written notice to the Secretary, request the Board of Directors to fix a record date. The Board of Directors shall promptly, but in all events within ten (10) days after the date on which such a request is received, adopt a resolution fixing the record date (unless a record date has previously been fixed by the Board of Directors pursuant to the first sentence of this Section 36).
■ **Proposals to be submitted for the 2015 Annual Meeting**	■ Deadline for proposal before the stockholders or nominate a director at the 2016 Annual Meeting of Stockholders: "if our 2016 Annual Meeting of Stockholders is held before May 17, 2016, or after July 16, 2016, to be timely, notice by the stockholder must be received no earlier than the close of business on the 120th day prior to the 2016 Annual Meeting of Stockholders and **not later than**

the close of business on the later of the 90th day prior to the 2016 Annual Meeting of Stockholders or the 10th day following the day on which public announcement of the date of the 2016 Annual Meeting of Stockholders is first made."

- The 2016 annual meeting date hasn't been set. Last year, MDVN filed the definitive proxy for the annual meeting on April 30, 2015 (a prelim proxy was filed on April 15, 2015). The Annual Meeting took place on June 16, 2015.

Key MDVN shareholders	%
FMR	14.5%
Vanguard	7.0%
Blackrock	6.5%
Wells Fargo	2.9%
Knoll Capital	2.7%
William Blair	2.3%
Discovery Capital	2.2%
State Street Corp	2.1%
AQR Capital	2.0%
Janus Capital	1.8%
Others	**56.0%**

Considerations for a takeover of MDVN

MDVN DESCRIPTION

MDVN pipeline

Target/Drug Compound	Indication	Status
XTANDI	metastatic CRPC	Commercial
Enzalutamide	non-metastatic CRPC	Phase 3
Enzalutamide	non-metastatic HSPC (rising PSA)	Phase 3
Enzalutamide	metastatic HSPC	Phase 3 (initiating)
Enzalutamide	hepatocellular carcinoma	Phase 2
Enzalutamide	AR+ TNBC	Phase 2
Enzalutamide	ER/PR+ & HER2 normal breast cancer	Phase 2
Enzalutamide	AR+ HER2 amplified breast cancer	Phase 2
Talazoparib (MDV3800)	gBRCA mutated advanced HER2 normal breast cancer	Phase 3
Pidilizumab (MDV9300)	Relapsed or refractory diffuse large B-cell lymphoma	Phase 2 (potentially pivotal)
MDV4463	Nonalcoholic steatohepatitis	Phase 1

Source: Bloomberg, company reports, and IGR.

MDVN is focused on the development and commercialization of medically innovative therapies to treat serious diseases for which there are limited treatment option. MDVN has one commercial product, XTANDI® (enzalutamide) capsules, or XTANDI, through MDVN's collaboration with Astellas. XTANDI has received marketing approval in the United States, Europe and numerous other countries worldwide for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC, and in Japan for the treatment of patients with castration-resistant prostate cancer, or CRPC.

- MDVN nd Astellas are also conducting investigational studies of enzalutamide in prostate cancer, advanced breast cancer, and hepatocellular carcinoma.
- Under the companies' collaboration agreement with Astellas, MDVN shares equally with Astellas all profits (losses) related to U.S. net sales of XTANDI.
    - MDVN also receives royalties ranging from the low teens to the low twenties as a percentage of ex-U.S. XTANDI net sales.
    - The collaboration also involved certain milestone payments from Astellas to MDVN upon the achievement of defined development, regulatory and sales events, all of which have been achieved as of December 31, 2015.
- **Enzalutamide Program:**
    - *Prostate cancer:* Once a patient has developed castration-resistant prostate cancer (CRPC), the typical second line therapy is a class of hormonal drugs known as anti-androgens, which block the ability of testosterone to bind its receptor. Bicalutamide, widely available in generic form, is the most commonly used anti-androgen drug. Bicalutamide treatment is typically discontinued once patients begin to progress on the drug.

- The next line of treatment for CRPC patients who have failed treatment on both LHRH analogs and anti-androgen drugs is frequently the chemotherapy drug Taxotere® (docetaxel), which has been shown in clinical studies to prolong survival. However, docetaxel is an infused cytotoxic chemotherapy, and thus entails an increased risk of serious adverse effects, including fluid retention, liver toxicity, low white blood cell counts, and death.
- Prior to 2010, there were no treatments approved by the U.S. Food and Drug Administration, or FDA, for CRPC patients whose prostate cancer had progressed following treatment with docetaxel. These patients typically had only palliative care, or pain reducing, options available to them. Since 2010, four new agents in addition to XTANDI have been approved by the FDA for the treatment of patients with mCRPC: Jevtana (cabazitaxel); Provenge (sipuleucel-T); Zytiga (abiraterone acetate) plus prednisone; and Xofigo (radium RA-223 dichloride); and others are currently being studied.
- Trials:
  - The Phase 2 TERRAIN trial was initiated in March 2011 and completed enrollment in July 2013. The trial evaluated enzalutamide head-to-head versus bicalutamide, the leading marketed anti-androgen drug, in 375 pre-chemotherapy mCRPC patients.
    - The Prescription Drug User Fee Act, or **PDUFA**, goal date for a decision by the FDA is **October 22, 2016.**
  - The Phase 2 STRIVE trial was initiated in August 2012 and completed enrollment in March 2014. The trial evaluated enzalutamide head-to-head versus bicalutamide, the leading marketed anti-androgen drug, in 396 pre-chemotherapy CRPC patients.
  - The **PDUFA** goal date for a decision by the FDA is **October 22, 2016**.
- The first patient was enrolled in the Phase 3 PROSPER trial in December 2013. The trial is evaluating the safety and efficacy of enzalutamide in patients with non-metastatic CRPC.
- The first patient was enrolled in the Phase 3 EMBARK trial in January 2015. The trial is intended to evaluate the efficacy and safety of enzalutamide alone or in combination with androgen deprivation therapy compared with androgen deprivation therapy alone in patients with high-risk, hormone-sensitive, non-metastatic prostate cancer that has biochemically recurred (rising PSA level) following definitive local therapy with radical prostatectomy and/or radiation.
- The Phase 4 PLATO trial was initiated in November 2013 and completed enrollment in September 2014. The trial is evaluating the efficacy and safety of continued treatment with enzalutamide plus abiraterone acetate and
- prednisone as compared to abiraterone acetate and prednisone alone in patients with chemotherapy-naive CRPC whose disease has progressed following enzalutamide therapy.
  - Top-line results from PLATO may be available as early as the second half of 2016.
- In January 2016, Astellas initiated start-up activities for a Phase 3 trial in patients with metastatic hormone-sensitive prostate cancer, or mHSPC

- *Breast cancer:*
  - Trials:
    - AR+, TNBC – This Phase 2 open-label, single arm, multicenter clinical trial evaluated enzalutamide as a single agent for the treatment of advanced androgen receptor positive
    - ER+ or PgR+ and HER2 Normal – The Phase 2 trial was initiated in December 2013 and completed enrollment of 247 patients in March 2015.
      - Top-line results from this trial may be available as early as the second half of 2016.
    - AR+ HER2 Amplified – In August 2014, Astellas initiated a Simon 2 stage Phase 2 clinical trial evaluating the safety and efficacy of adding enzalutamide to trastuzumab in approximately 80 patients with advanced breast cancer that is AR+ and HER2 amplified
- *Hepatocellular Carcinoma:* In January 2016, Astellas enrolled the first patient into a Phase 2 trial evaluating enzalutamide in hepatocellular carcinoma. The trial will assess approximately 144 patients with advanced hepatocellular carcinoma that have failed sorafenib or other anti-vascular endothelial growth factor therapies. The primary endpoint of the trial is overall surviva

- **MDV3800 (talazoparib) program:**
  - MDV3800 is an orally available poly-ADP ribose polymerase, or PARP, inhibitor currently in a Phase 3 clinical trial for the treatment of patients with gBRCA mutated breast cancer. The Phase 3 EMBRACA trial is an open-label, 2:1 randomized, parallel, two-arm study of MDV3800 as compared to the protocol-specified physicians' choice of chemotherapy (capecitabine, eribulin, gemcitabine or vinorelbine) in gBRCA-mutated locally advanced and/or metastatic breast cancer patients who have received prior chemotherapy for their metastatic disease.
    - The primary objective of the study is to compare PFS of patients treated with MDV3800 as a monotherapy relative to those treated with protocol-specified physicians' choice.

        - MDVN anticipates fully enrolling this trial by the end of 2016 with top-line results as early as the first half of 2017.

- **MDV9300 (pidilizumab) program:**
    - MDV9300 is an antibody with immune-mediated anti-tumor effects, for all potential indications. MDV9300 was not generated against a single purified recombinant protein but, rather, was generated against a lymphoblast cell line called DAUDI. Although the molecule was originally understood to work primarily via PD-1 (Programmed Death-1) binding, MDVN's work as well as that of others has shown other potential activity as well.
    - Prior to concluding non-binding of PD-1, in 4Q/2015, MDVN initiated a Phase 2 clinical trial evaluating MDV9300 in patients with relapsed or refractory diffuse large B-cell lymphoma, or DLBCL
    - In early January 2016, MDVN promptly advised FDA of MDVN's conclusion that MDV9300 does not bind PD-1, and the agency placed the IND on partial clinical hold and requested that MDVN revises its characterization of MDV9300 in the related investigator brochure, protocols and informed consent documents.
        - MDVN since submitted the revised documents in early February 2016.
        - On March 9, 2016 MDVN announced that the FDA lifted the partial clinical hold on MDV9300 in hematological malignancies and confirmed that the Phase II clinical trial in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), as well as other studies that cross reference the IND, may now proceed.
- **Patents:**
    - XTANDI: MDVN has an exclusive license to multiple issued patents and pending patent applications covering XTANDI, related compounds and uses thereof, including issued composition of matter patents covering XTANDI in the United States, Europe, and Japan.
        - The terms of these issued XTANDI composition of matter patents have a base expiry in 2027 in the United States and in 2026 in Europe and Japan.
        - Supplemental Protection Certificates, or SPCs, and patent term extensions are pending or have been granted in Europe and Japan.
    - MDV9300: MDVN has an exclusive license to multiple issued patents and pending patent applications covering MDV9300, including the antibody and methods of use of MDV9300.
        - In addition, MDVN expects to rely on the 12 years of data exclusivity available for biologic products.
    - MDVN's acquisition of worldwide rights to MDV3800 included issued patents, pending patent applications and know-how covering MDV3800's composition of matter as well as methods of use and methods of manufacturing MDV3800.

Key competitors: Many products currently compete or are expected to compete with XTANDI for the treatment of advanced prostate cancer.

- **Prostate cancer:** Products approved for advanced prostate cancer include Casodex® (bicalutamide), which is widely available in generic form and its generic pricing constitutes a competitive advantage relative to any branded drugs that are, or may later be, approved to treat pre-chemotherapy or non-metastatic CRPC or HSPC; Jevtana® (cabazitaxel); Provenge® (sipuleucel-T); Zytiga® (abiraterone acetate) plus prednisone; and Xofigo® (radium RA-223 dichloride).
    - Drugs still in development for advanced prostate cancer include apalutamide (formerly JNJ-56021927, or JNJ-927, and ARN-509) by Johnson & Johnson's subsidiary Aragon Pharmaceuticals, or Aragon; ODM-201, which is being developed by Bayer and Orion Corporation; and galeterone (formerly TOK-001) which is being developed by Tokai.
- **Breast cancer:** There are many products available or currently in development for patients with breast cancer and which could compete with enzalutamide for the treatment of advanced breast cancer,
    - Bicalutamide – Bicalutamide is approved for prostate cancer and is being studied in several Phase 2 studies in androgen receptor-positive breast cancer. Positive proof-of-concept with enzalutamide or other drugs targeting androgen receptor signaling may encourage spontaneous use of bicalutamide in breast cancer.
    - IbranceTM (palbociclib) – Pfizer's kinase inhibitor targeting CDK4/6 is approved in combination with letrozole or with fulvestrant for estrogen receptor-positive, HER2-negative, advanced breast cancer.
    - Pembrolizumab – Merck's monoclonal antibody targeting PD-1 is being studied in a randomized Phase 3 study comparing the effects of pembrolizumab against investigator's choice chemotherapy in patients with metastatic triple-negative breast cancer who have received 1-2 prior therapies for metastatic disease.
    - Atezolizumab – Roche's monoclonal antibody targeting PD-L1 is being studied in a randomized Phase 3 study comparing the effects of atezolizumab in combination with nab-paclitaxel against nab-paclitaxel in patients with previously untreated, metastatic, triple-negative breast cancer.
    - Enobosarm – GTx Therapeutics' investigational androgen receptor modulator is being studied in a Phase 2 open-label trial to assess preliminary efficacy in advanced triple-negative breast cancer patients whose tumors are deemed positive for androgen receptor expression.
- **MDV3800** faces competition from other PARP inhibitors, including:
    - Lynparza (olaparib) – AstraZeneca's product is approved for patients with deleterious or suspected deleterious gBRCA mutated advanced ovarian cancer. Olaparib is being studied in a Phase 3 trial comparing the effects of olaparib against investigator's choice chemotherapy in metastatic, HER2-negative breast cancer patients with deleterious germline BRCA1/2 mutations, and in Phase 2 studies for several other tumor types.

- Rucaparib is an investigational PARP inhibitor being developed by Clovis Oncology.
- Veliparib is an investigational PARP inhibitor being developed by AbbVie. It is currently in Phase 3 clinical trials for the treatment of HER2-negative, germline BRCA1/2-mutated breast cancer and non-small cell lung cancer, and Phase 2 studies for a variety of other cancers.
- Niraparib is an investigational PARP inhibitor being developed by Tesaro. It is currently in Phase 3 clinical trials for ovarian cancer and BRCA+ breast cancer.

- **MDV9300** will face strong competition from other immuno-oncology agents.
  - The immuno-oncology field is competitively crowded with more than 100 drug therapy agents, including biologic molecules, vaccines, modified T-cells, and adjuvants, in development for various tumor types and patient populations by larger more experienced companies than MDVN's, such as Bristol Myers Squibb, Roche, AstraZeneca, Pfizer and Merck.
    - Specifically in DLBCL, MDV9300's development and commercialization may face competition from Bristol Myers Squibb's monoclonal antibody nivolumab (targeting PD-1), currently being studied in a potentially registrational Phase 2 study in relapsed/refractory DLBCL patients.

March-in rights & XTANDI: The Union for Affordable Cancer Treatment (UACT) and Knowledge Ecology International sent a letter to the Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and/or the Department of Defense (DoD).

- At issue is the cost of Xtandi, which is sold by Astellas Pharma and has an average wholesale price in the US of more than $129,000, about two to four times more than what other high-income countries are paying, according to the Union for Affordable Cancer Treatment and Knowledge Ecology International. They sent their letter to the NIH, as well as to the US Department of Health and Human Services and the US Department of Defense.
  - Compared with the wholesale price in the US, where a 40-milligram capsule costs $88.48, Xtandi costs $23.46 in Australia, $20.12 in Canada, and $32.43 in Norway. Medicare, by the way, pays $69.41, according to the advocacy groups.
- In their view, the Xtandi patent should be overridden because Xtandi was developed at the University of California, Los Angeles, with help from taxpayer dollars — specifically, NIH and Department of Defense grants. They note that one of the chief inventors of the drug was a UCLA professor and the university later licensed the drug to Medivation, a biotech that eventually struck a marketing deal with Astellas.
- The Affordable Drug Pricing Task Force later argued the NIH has the ability to issue so-called march-in rights, which refer to overriding a patent. Under federal law, the lawmakers wrote, this allows an agency that funds private research to require a drug maker to license its patent to another party in order to "alleviate health and safety needs which are not being reasonably satisfied" or when the benefits of a drug are not available on "reasonable terms."

In March 2016, Rep. Lloyd Doggett (D-TX) and a group of other lawmakers--including Sen. Bernie Sanders (I-VT) and Elijah Cummings (D-MD), who've been leading investigations into pharma pricing, asked Burwell and NIH Director Francis Collins to hold an "open and transparent" public hearing on pricing for Xtandi.

- In 2013, NIH denied a similar petition from advocacy groups, including Knowledge Ecology International, which complained that the price of an AIDS medicine developed with federal
  - The NIH "in 35 years has never agreed with a request for march-in rights, particularly in the context of high drug prices," Dr. Aaron Kesselheim, an associate professor of medicine at Harvard Medical School said.

STRATEGIC DRIVERS

Strategic drivers: We believe that there are three drivers for the deal: i) potential to increased penetration for XTANDI; ii) potential for indication expansion; and iii) promising oncology pipeline.

- Xtandi is currently only penetrating a fraction of addressable prostate cancer population, although revenue growth has slowed down earlier than expected.
  - It is expected that TERRAIN and STRIVE approval will increase adoption by urologists who prescribe 85% of anti-androgens.
  - Currently, XTANDI is expected to generate $2bn peak revenue, however, this could be expanded through indication expansion and increase in penetration.
    - It has been argued that XTANDI's revenue opportunity could be in the $6bn to $8bn range.
      - A recent XTANDI royalty sale by UCLA implied ~$5bn worldwide XTANDI sales by 2020.
    - Multiple Phase 2 and 3 trials underway to expand the indication of Xtandi to other forms of prostate cancer (focusing on earlier within the disease course), breast cancers, and liver cancer (i.e., hepatocellular carcinoma).
- The two key pipeline assets are MDV3800 and MDV9300.
  - MDV3800 was highlighted as a potential best in class PARP inhibitor.
    - There are multiple potential focus indications for talazoparib, including breast, prostate, and ovarian cancers
    - Peak U.S. revenue for talazoparib could be between $800m to $2.0bn depending on indication expansion and efficacy.
- We note that analysts have not really attached much value to XTANDI label expansion and the MDVN pipeline.

- However, MDVN offers a strong upside opportunity to potential buyers.

Potential bidders for MDVN: We believe that the most obvious buyers are likely to be Sanofi, AstraZeneca, Roche, Bayer, and Astellas.

Potential cost savings

FY2015	(m)	% savings	Total saving
R&D Expenses	$232	40%	$93
SG&A	$297	50%	$148
Total	**$529**		**$241**

Source: Bloomberg, company reports, and IGR.

Cost savings: We estimate **annual cost savings of $240m** for a competitor. We see two sources for cost savings:

- R&D expenses and SG&A. We note that operating costs would likely increase over time and therefore the long-term synergy potential is likely to be ~$500m.
- We estimate NPV of cost savings of $9.4 per MDVN share, assuming
  - Annual cost savings of $240m
  - Cost of synergies of $250m
  - Capitalization at 10x
  - Tax rate at 25%.

Tax savings: We note that for a foreign buyer there may be some upside to MDVN's tax rate. MDVN's tax rate is likely to be one of the highest one among U.S. peers. MDVN's tax rate is likely to increase to 35% absent any tax optimization strategy.

Valuation of MDVN

TAKEOUT VALUE

ROIC calculations

Deal value	2021
Bid price ($/sh.)	*$75.00*
O/S (m)	*164*
Market value ($m)	**$12,318**
Net Debt ($m)	-$129
Deal value ($m)	**$12,189**
ROIC calculation	
BEST Operating Profit (BEST median)	**$1,239.7**
Synergies	*$240*
Adj. Operating Profit	**$1,480**
Tax (35%)	*$518*
NOPAT	**$962**
ROIC	**7.9%**
WACC	**8.0%**

Source: Bloomberg, company reports, and IGR.

By our ROIC calculations and targeting WACC of 8.0%, we estimate that in a competitive bidding situation, MDVN may fetch as much as $75 per share.

- We note that our ROIC analysis does not attach much value to XTANDI's expansion potential and to MDVN's pipeline. We also assumed no tax savings for a foreign buyer.
- We did assume annual cost savings of $240m (approximately 28% of forecast FY2021E operating costs of MDVN).

RISK-REWARD

We believe that the risk-reward for a position long MDVN (or alternatively June 55 Calls) appears to be attractive.

- MDVN's standalone value is likely to have been rerated. Assuming 7.0x FY2016E EV/Sales, we estimate MDVN standalone value at $40 per share.
  - The next key catalysts for MDVN come in 2H/2016.

- We estimate that MDVN may fetch as much as $75 per MDVN share through a bidding process.
- We believe that MDVN is a unique asset offering significant upside potential through expansion of label for its marketed product, XTANDI (in addition to further growth potential from increasing penetration) and its pipeline.
- There appear to be several bidders for the company, and a bidding war for a strategic asset makes the upside potential even more attractive.
    - Standstill with Astellas expires in September 2016.
- We also note that apart from a poison pill, MDVN does not appear to have any other takeover defenses.

Management appears to be incentivized to maximize shareholder value.

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