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# AV Therapeutics, Inc.
OTCQB: AVTH

**February 8, 2015**
**Target Price: $0.24**
**Recent Price: $0.04**

### Market Data

| | |
|---|---|
| Fiscal Year | December 31 |
| Industry | Biotech |
| Market Cap | $3.3M |
| Price/Earnings (ttm) | N/A |
| Price/Book (mrq) | N/A |
| Price/Sales (ttm) | N/A |
| Insider Ownership | 61.1% |
| Shares Outstanding | 81.9M |
| Float | 31.8M |
| Avg. Daily Vol. (3 mos.) | 83,932 |

*As of February 5, 2015*

### Income Snapshot

| | TTM |
|---|---|
| Revenue | $0.0M |
| EBITDA | ($1.6M) |
| Net Loss | ($1.7M) |

### Balance Sheet Snapshot

| | MRQ |
|---|---|
| Cash | $0.3M |
| Debt | $0.3M |

### Company Website
http://www.avth.net/

## Company Overview

AV Therapeutics, Inc. is engaged in the business of developing cancer therapeutics and immunotherapeutic vaccines that can be used alone or in combination with prevalent treatment modalities, such as chemotherapy and radiation, to treat active disease and to prevent metastases and recurrence. The Company's immune-therapeutics is based on the ability of certain proprietary reagents to re-educate or reprogram an immune system that can target previously unidentified micro-metastases. The Company intends to clinically develop both of these approaches for metastatic and early-stage prostate cancer.

## Value Proposition

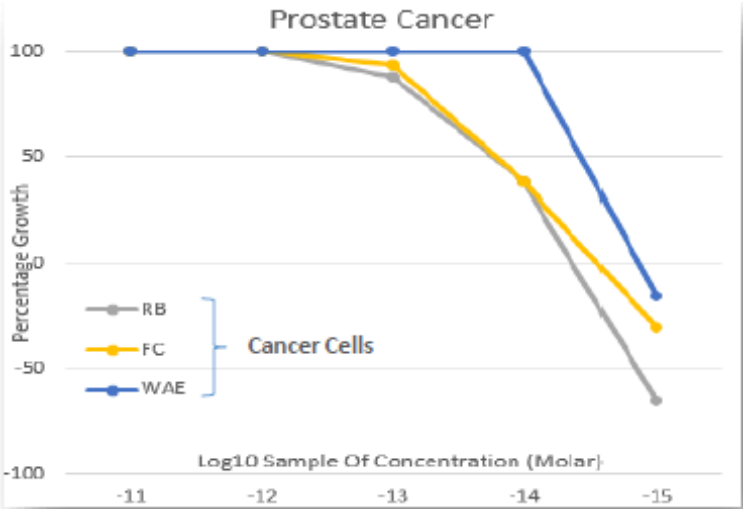
We are projecting AVTH shares at $0.24, based on a risk adjusted NPV on Capridine-β for prostate cancer.

## Investment Highlights

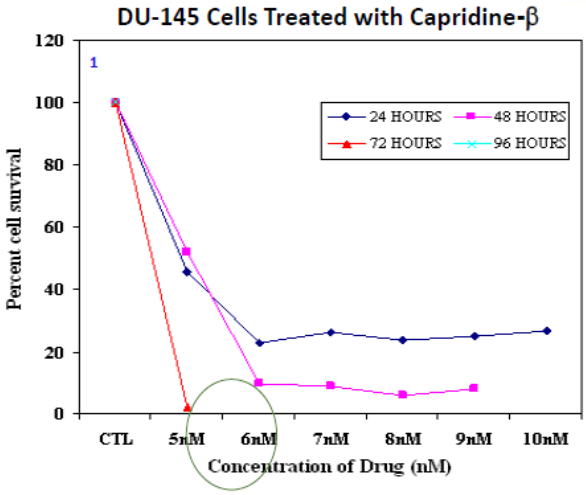
- Capridine-β uniquely exhibits prostate cancer (PCa) specificity, distinguishing it from currently available prostate cancer treatments
- Capridine-β has activity against both hormone dependent and refractory PCa cells
- Low bone marrow toxicity improves odds of success, and could make it more amenable for various stages of prostate cancer
- Investors and government agencies, including the Department of Defense and National Institutes of Health, have invested over $7 million into developing and testing Capridine-β
- Successful completion of GMP synthesis of Capridine-β; expected to commence phase I clinical trials in 1Q16
- U.S. prostate cancer market projected to reach $8.6 billion by 2022
- Treatments for advanced prostate cancer are currently limited
- Potential for Capridine-β beyond prostate cancer
- Capridine-β and 200 of its derivatives are patent protected in the U.S., EU, Mexico, Canada, and Israel
- AVTH has developed a peptide-based therapeutic vaccine that is designed to eliminate micrometastatic and residual disease, hence preventing cancer recurrence

## Investment Highlights

**Capridine-β uniquely exhibits prostate cancer (PCa) specificity, distinguishing it from currently available prostate cancer treatments.** In preclinical studies, Capridine has shown an ability to specifically target prostate cancer cells, allowing it to home in and attack prostate cancer at the source.




Capridine-β showed a pronounced anti-tumor effect in DU-145 (prostate cancer cell line with moderate metastatic potential) cells. The graph below demonstrates the effects of varying doses of Capridine-β at different time intervals. As demonstrated, the percentage of cancer cells that survive decreases significantly as the time variable increases while there is a plateau effect dependent on the dose administered. This indicates that a low amount of the drug leads to high efficacy.




Western blot analysis of the DU-145 cells treated with Capridine-β show elevation of cyclin-dependent kinase inhibitor 2a (p16) and downregulation of cyclin-dependent kinase 4 (cdk4). P16 is a tumor suppressor gene that inhibits a cell's progression from G1 to S phase of the cell cycle by preventing CDK4 & CDK6 from binding to cyclin D. By preventing cells from progressing to S phase, it inhibits the initiation of mitosis (where cells duplicate into two identical daughter cells), thus inhibiting the duplication of cancer cells. It is interesting to note that Capridine-β also downregulates cdk4 expression through an alternative mechanism, further inhibiting cell cycle progression. This dual-action mechanism demonstrates that Capridine-β selectively inhibits cell division in two different ways during a critical milestone step. By inhibiting this process, Capridine-β prevents the target (prostate cancer) cells from replication and proliferation.

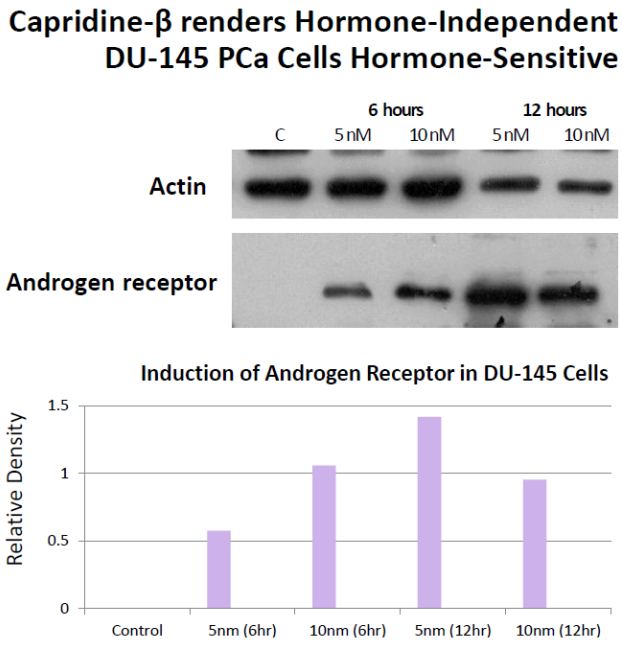
As detailed below, this PCa specificity could help lead to a number of advantages for Capridine-β versus current chemotherapy treatments.

**Capridine-β has activity against both hormone dependent and refractory PCa cells.** Taxanes are a common chemotherapeutic regimen used in treating prostate cancer. Examples of taxanes that are commonly used to treat prostate cancer into docetaxel (Taxotere) and cabazitaxel (Jevtana). In many instances the prostate cancer cells are resistant to taxane rendering it ineffective or only marginally effective in treating the disease.

As indicated in the below chart, both hormone dependent (LnCap) and refractory (PC-3 and DU-145) cells are more sensitive to Capridine-β as opposed to taxanes.

| Cell lines | $IC_{50}$ Values (nM) | |
|---|---|---|
| | Taxane | Capridine |
| LnCaP | >100nM | 15nM |
| PC3 | 16-20nM | 5nM |
| DU145 | 15-20nM | 5nM |

This is crucial for a number of reasons. Taxanes such as docetaxel have shown limited efficacy against LnCap cells; based on preclinical data, Capridine-β could provide a superior treatment for these cells. Additionally, Capridine-β has shown superior activity against hormone-independent cells (PC3 & DU-145).



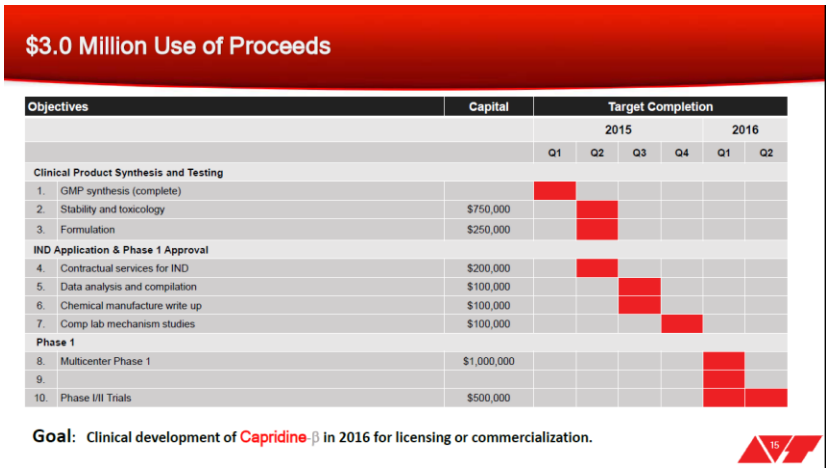

Capridine-β has also shown the ability to turn hormone-independent DU-145 PCa cells hormone-sensitive. This could prove crucial, as reinduction of the androgen receptor could improve the effectiveness of hormone therapy, thus growing and improving possible patient treatment options.

**Low bone marrow toxicity improves odds of success, and could make it more amenable for various stages of prostate cancer.** In preclinical studies, Capridine-β has shown very low bone marrow toxicities. This is crucial for a few reasons. This is another indicator that Capridine-β is a very targeted therapy, as seen by its strong specificity for PCa cells. Additionally, this indicates that the therapy is safer than other agents currently being used on the market. We believe that this could make Capridine-β eligible for use in multiple stages of prostate cancer care (stages 2-4) either as a standalone therapy or in conjunction with other treatments (likely in earlier stages; this could also help prevent resistance to other treatments).

**Investors and government agencies, including the Department of Defense and National Institute of Health, have invested over $7 million into developing and testing Capridine-β.** These funds have led to significant pre-clinical research on Capridine-β and has positioned AVTH to enter phase I clinical trials shortly.

**Successful completion of GMP synthesis of Capridine-β; expected to commence phase I clinical trials in 1Q16.** AVTH recently completed GMP synthesis of Capridine-β, with the product showing 99.8% purity and great conformity. This GMP product was used to create a limited toxicity profile, which is currently being analyzed by AVTH.

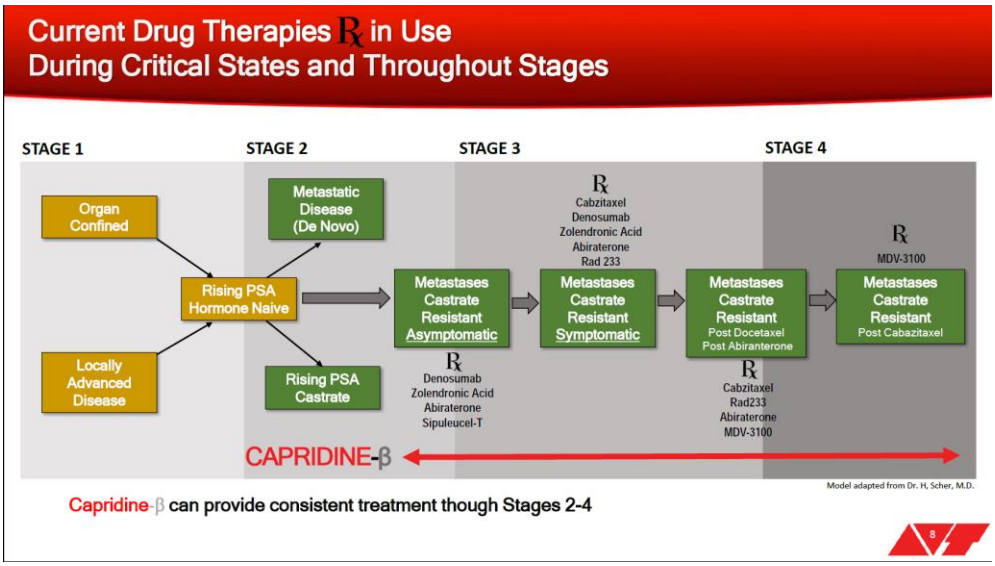
AVTH is expected to begin phase I clinical trials in 2015, following the completion of preclinical studies and an IND application. Following completion of the toxicology profile, AVTH estimates needing $750,000 to enter phase I clinical trials, along with an additional $1.5 million for phase I/II trials.




**U.S. prostate cancer market projected to reach $8.6 billion by 2022.** According to the American Cancer Society, prostate cancer is the most common type of cancer in men in the U.S. 1 in 7 men are diagnosed with prostate cancer and 1 in 36 die from it. It is predicted that in 2014, there will be more than 233,000 new cases of prostate cancer and 29,480 deaths. According to Decision Resources, the prostate cancer drug market will reach $8.6 billion globally by 2022. A strong proportion of this growth will be due to a rise in men living with metastatic prostate cancer; a prior report from Decision Resources projected that men living with metastatic prostate cancer would rise from 195,000 in 2010 to 520,000 in 2025.

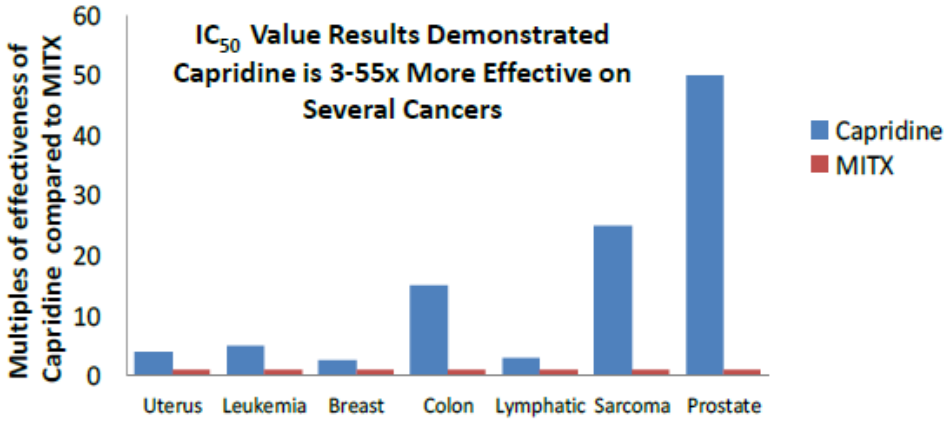
**Treatments for advanced prostate cancer are currently limited.** While advancements in prostate cancer treatments have occurred over the past few decades, there are currently no treatments that can cure advanced prostate cancer. Endocrine therapy (hormone therapy), is typically the first line of treatment. Most patients with advanced prostate cancer eventually stop responding to hormone therapy; the next line of treatment is typically chemotherapy. Typically patients receive docetaxel (Taxotere), which has a side effect profile common to most chemotherapy drugs, such as nausea, hair loss, and bone marrow suppression. 2004 clinical trial results showed that docetaxel improved survival by 2.5 months when compared to mitoxantrone. If prostate cancer continues to progress, then typically the chemotherapy drug cabazitaxel (Jevtana) is used. Side effects include neutropenia, anemia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, weakness, and renal failure. The median overall survival for patients receiving cabazitaxel was 15.1 months, compared to 12.7 months for patients that received mitoxantrone. We believe that Capridine-β's main

market competition will ultimately be against docetaxel and cabazitaxel. Taxotere worldwide annual sales peaked in 2010 with sales of $3.1 billion (loss of patent protection contributed to sales declines following 2010).




Additional drugs used in prostate cancer treatment include sipuleucel-T (Provenge), an immunotherapy that uses a patient's own cells as a vaccine, and abiraterone acetate (Zytiga) and enzalutamide (Xtandi). Abiraterone acetate and enzalutamide are antiandrogens that are used to block the effect of testosterone in the body. These drugs are projected to drive most of the new drugs sales in prostate cancer over the next several years.

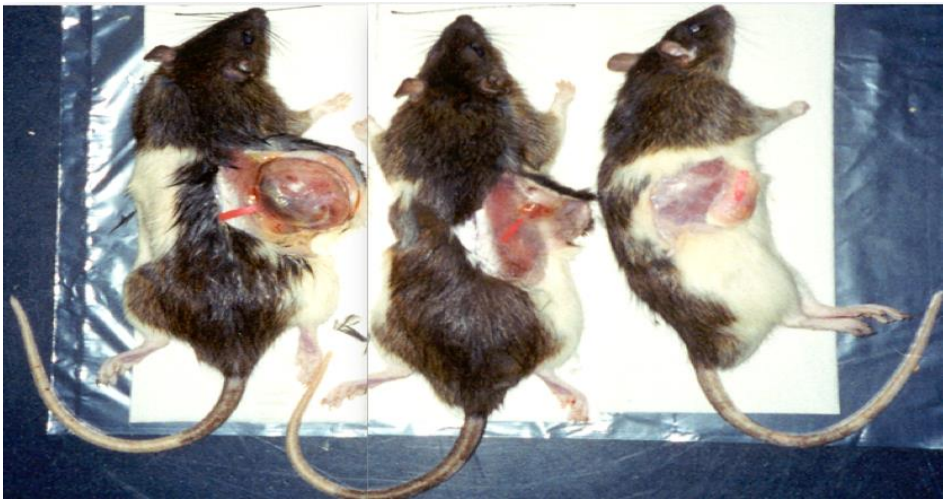
**Potential for Capridine-β beyond prostate cancer.** The $IC_{50}$ value has demonstrated that Capridine-β is between 3-55 times more effective on several cancers than mitoxantrone. $IC_{50}$ is a measure of the effectiveness of a substance in inhibiting a specific biological or biochemical function. In cancer, mitoxantrone is used primarily to treat metastatic breast cancer, acute myeloid leukemia, and non-Hodgkin's lymphoma, along with being used as a second-line treatment for metastatic hormone-refractory prostate cancer.




These results indicate that Capridine-β has the potential to build a long-term therapy platform over time, specifically in colon cancer and sarcoma.

**Capridine-β and 200 of its derivatives are patent protected in the U.S., EU, Mexico, Canada, and Israel.** This patent protection should allow the Company to market its prostate cancer treatment in most of the world's major markets, along with protecting other potential indications. The Company has been awarded two patents for Capridine-β, two patents for its Pros-Vox vaccine, and one patent pending for its Pros-Vox vaccine in the U.S.

**AVTH has developed a peptide-based therapeutic vaccine that is designed to eliminate micrometastatic and residual disease, hence preventing cancer recurrence.** AVTH's peptide vaccine Pros-Vax mimics cancer proteins and induces an immune response against multiple cancer-specific proteins. AVTH's peptide-based vaccine is unique in that it re-educates the immune system allowing cancer cells to be recognized and killed, and it prevents the constant generation of random mutations in cellular proteins, hence preventing recurrence. The vaccine is an easily manufactured, small molecule drug. Pre-clinical studies demonstrate that animals vaccinated with the peptides showed inhibition of prostate cancer cell growth of over 90%. In the future, AVTH intends on combining Capridine-β with one of its peptide-based immunotherapeutic vaccines in order to design a unique treatment for prostate cancer. The picture below demonstrates results of a study on the effects of immunization with the peptide vaccine in subjects with metastatic prostate cancer. The mouse on the left is unimmunized while the other two mice are immunized with two different derivatives of the vaccine. As demonstrated, there is substantial metastatic prostate cancer growth in the unimmunized rat when compared to the other two mice.



A possible advantage of vaccine-based treatment has been that limited side effects have been seen to date. There are multiple vaccines being tested to treat prostate cancer in clinical trials, and sipulecuel-T (Provenge) has already received FDA approval. Provenge earned annual sales of approximately $300 million in 2014, and following the recently announced bankruptcy by Dendreon Corp., Provenge's drug rights were acquired by Valeant Pharmaceuticals for $296 million.

## Valuation

We are projecting AVTH shares at $0.24, based on a risk adjusted NPV on Capridine-β for prostate cancer. A few notes on our valuation:

- We are currently only modeling the use of Capridine-β for metastatic prostate cancer. Additional value may be prescribed in the future if AVTH begins to develop Capridine-β for other indications, or if further development occurs in its Pros-Vox vaccine
- We are projecting sales of Capridine-β to begin in 2026
- We are estimating peak market share to occur in 2030 (3.5% of metastatic prostate cancer patients), and then maintaining that market share for an additional five years
- We are calculating our rNPV using a discount rate of 10.0% and a probability of commercialization of 3%. The low probability of commercialization percentage is due to the fact that Capridine-β is still in preclinical trials

| U.S. Market | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Patients WW with Metastatic Prostate Cancer | 263,477 | 281,288 | 300,303 | 320,604 | 342,276 | 365,414 | 390,116 | 416,488 | 444,643 | 474,701 | 506,790 | 541,049 | 577,624 | 616,672 | 658,359 | 702,864 | 750,377 | 801,103 | 855,257 | 913,073 | 974,797 |
| Penetration % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.5% | 1.5% | 2.5% | 3.0% | 3.5% | 3.5% | 3.5% | 3.5% | 3.5% | 3.5% |
| Patients treated | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2,705 | 8,664 | 15,417 | 19,751 | 24,600 | 26,263 | 28,039 | 29,934 | 31,958 | 34,118 |
| Revenue per patient | $33,000 | $33,990 | $35,010 | $36,060 | $37,142 | $38,256 | $39,404 | $40,586 | $41,803 | $43,058 | $44,349 | $45,680 | $47,050 | $48,462 | $49,915 | $51,413 | $51,413 | $51,413 | $51,413 | $51,413 | $51,413 |
| Annual Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $123.6M | $407.7M | $747.1M | $985.9M | $1264.8M | $1350.3M | $1441.5M | $1539.0M | $1643.0M | $1754.1M |
| Operating Margin | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 35% | 35% | 35% | 35% | 35% | 35% | 35% | 35% | 35% | 35% |
| Drug Development Costs | $0.8M | $1.5M | $3.0M | $15.0M | $15.0M | $15.0M | $5.0M | $30.0M | $30.0M | $30.0M | $10.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M | $0.0M |
| **Cash Flows** | **-$0.8M** | **-$1.5M** | **-$3.0M** | **-$15.0M** | **-$15.0M** | **-$15.0M** | **-$5.0M** | **-$30.0M** | **-$30.0M** | **-$30.0M** | **-$10.0M** | **$43.3M** | **$142.7M** | **$261.5M** | **$345.1M** | **$442.7M** | **$472.6M** | **$504.5M** | **$538.6M** | **$575.1M** | **$613.9M** |

| | |
|---|---|
| Discount Rate (10.0%) | |
| NPV ($MM) | $667.1M |
| Probability of commercialization | 3% |
| rNPV | $20.0M |
| Diluted Shares Outstanding | 81,880,963 |
| rNPV Per Share | **$0.24** |

## Risks

**There is no guarantee that AVTH will enter human clinical trials for Capridine-β.** AVTH still has to complete preclinical studies and receive FDA approval to begin phase I clinical trials.

**AVTH's future capital needs are uncertain.** Drug development costs are typically significant, and it is currently uncertain how much capital AVTH will need during drug development, and how the Company will attain this capital. Equity raises would dilution current shareholders, and if AVTH enters into development agreements with other pharmaceutical and biotech companies, deal terms could adjust the potential value of AVTH stock.

**There is no guarantee that AVTH's drugs will be economically feasible.** Drug manufacturing and marketing costs may be higher than anticipated, which could make AVTH's drugs uneconomic even if it passes all of its clinical trials and receives FDA approval.

**AVTH relies on third parties to help conduct its development program.** If the third parties fail to perform their obligations in a timely or competent manner development of the therapies could be delayed. Delays in this process could also cause the Company to need additional capital.

## Additional Information

Legal: Sichenzia Ross Friedman Ference LLP
Auditor: Marcum, LLP
Transfer Agent: Globex Transfer, LLC

Company Website
Company Information

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