PDS Biotechnology

Midyear Review: Has PDS Turned The Corner?

Jul 09, 2024

Healthcare

PDSB

NCM

Rating

Outperform

Unchanged

Current Price

$3.23

Target Price

$17.00

Market Capitalization
118.47m

Shares Outstanding
36.68m

Float
33.19m

Institutional Holdings
20.75%

12-Month Low/High
$2.53/$6.85

Average 90-Day Volume
651740

Fiscal Year End
2024-12-31

Revenues ($ MIL)

Period	2022A	2023E	2024E
Q1	0.0	0.0A	0.0E
Q2	0.0	0.0A	0.0E
Q3	0.0	0.0A	0.0E
Q4	0.0	0.0E	0.0E
	0.0	0.0E	0.0E

EPS ($)

Period	2022A	2023A	2024E
Q1	(0.32)	(0.32)A	(0.34)E
Q2	(0.20)	(0.37)A	(0.35)E
Q3	(0.26)	(0.35)A	(0.37)E
Q4	(0.61)	(0.34)A	(0.35)E
	(1.43)	(1.38)A	(1.41)E

Amended Phase 3 Clinical Trial Will Test Two Drugs. During 2Q24, the design of the Phase 3 trial testing Versamune HPV with Keytruda added a second treatment arm to test Versamune, PDS01ADC, and Keytruda against the active control arm of Keytruda alone. We believe this new trial design answers several questions that have caused PDSB to stagnate over the past year. A meeting with the FDA to ensure alignment on the trial design is expected during July 2024.

Thoughtful Consideration Has Led To Improved Trial Design. There are several points from the Phase 2 trial data that lead us to believe that adding the third arm to Phase 3 study improves its design. We believe the Triple-combination could have more rapid enrollment, produce data for product approvals, and support extensive use as a first-line therapy.

PDS Phase 3 Combination Addresses The Two Main Reasons For Treatment Failure. The current standard of care for HNSCC is a checkpoint inhibitor, either Keytruda (pembrolizumab, Merck) or Opdivo (nivolumab, Bristol-Meyers). These drugs improve survival but have low response rates attributed to (1) the lack of immune cells in the tumor and (2) the inability of the immune system to generate populations of effective tumor-killing cells withing the tumor microenvironment. The Triple-combination therapy regimen with Versamune HPV and PDS01ADC has actions inside and outside the tumor to overcome both problems.

Additional Indications Continue To Advance. Versamune HPV and PDS01ADC are currently in additional Phase 2 trials with other regimens and tumor types expected to report data updates during 2H24. These trials include a Phase 2 trial testing Versamune HPV in locally advanced cervical cancer and a neoadjuvant trial testing Versamune HPV in locally advanced oropharyngeal cancer (OPSCC). Additional preclinical products using the Versamune technology in other tumors and infectious diseases have been tested in preclinical studies.

Conclusion. We continue to believe that both Versamune HPV and PDS01ADC can make significant contributions to overall survival and patient outcomes. Although this has delayed the start of the trial, we believe the new trial could lead to approval of both drugs. We are reiterating our Outperform rating and $17 price target.

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PDS Biotechnology (PDSB) | Current Price: $3.23 | Outperform | Jul 09, 2024

Midyear Review: Has PDS Biotech Turned The Corner?

Summary: PDS made an important change to the design of the Phase 3 trial testing Versamune HPV in combination with Keytruda (pembrolizumab, a PD-1 checkpoint inhibitor from Merck). It has added a second treatment arm testing Versamune, PDS01ADC, and Keytruda against the active control arm of Keytruda alone. Management has planned a meeting with the FDA to ensure alignment on the trial design for later in July 2024. This would allow the trial to begin toward YE2024.

We believe this additional arm of the trial could lead to approvals of both Versamune HPV and PDS01ADC from a single trial, with potential to establish the Triple-combination therapy as the best regimen for head and neck HPV16+ cancer. In June, PDS announced an update to the Phase 2 VERSATILE-002 data that further supports the efficacy and safety seen in previous analysis. Additional Investigator Initiated Trials (ITTs) using Versamune HPV in different regimens and other HPV-related tumors are expected to announce data updates in 2H2024.

June 2024 Update For VERSATILE-002 Phase 2 Regimen Data Shows Best Survival. PDS updated the results of the Phase 2 VERSATILE-002 study through a May 2024 analysis point. Median overall survival (mOS) is still 30 months and remains consistent with the data update announced on November 30, 2023. Some patients are reaching the 3-year survival milestone, with 27 of the patients alive and followed for survival. This is a substantial improvement over the 17.9 months survival from Keytruda monotherapy seen in a recent study. The complete analysis of the May 2024 evaluation point is expected during 2H2024.

KOL Event Discussed The Trials and New Phase 3 Design. In May 2024, PDS Biotech announced changes to the design of its Phase 3 trial in head and neck cancer (HNSCC, head and neck non-squamous cell carcinoma). The study, to be known as the "VERSATILE-003 PLUS" trial, will include three arms that test both Versamune HPV and PDS01ADC in combination with Keytruda. The company held a KOL webcast to discuss HPV16-positive cancer, the Phase 2 trials, and the changes to the Phase 3 trial. Noble Capital also hosted a non-deal roadshow where the company was able to answer investors' questions about the trial, the pipeline, and the markets served by the products.

The oncologists on the webcast reviewed head and neck cancer, its current treatments, and the data from the Phase 2 trials testing Versamune HPV (formerly PDS0101) and PDS01ADC in combination with Keytruda. They also made several insightful points about the advantages of the new three-arm trial design over the previous two-drug design. As discussed below, these changes should lead to faster enrollment in the trials and the best outcomes for patients.

FDA Guidance Meeting Is Planned For July 2024. The previous design, known as VERSATILE-003, was planned as a two-arm trial testing Versamune HPV with Keytruda against Keytruda alone in patients that had not previously received an immune checkpoint inhibitor (ICI naïve). The study followed the design of the Phase 2 VERSATILE-002 trial that had shown significant benefits, with endpoints that followed FDA guidance for approval. We believed that success in this trial would have allowed Versamune HPV to reach the market, to be followed by a second Phase 3 trial using the triple-combination in patients that had failed checkpoint inhibitor therapy (ICI refractory).

As the VERSATILE-003 trial was in the planning stage, additional data from the Phase 2 Triple-therapy trial became available. This trial, known as the "Triple-combination" or "NCI study" added the immune stimulator PDS01ADC to the combination of Versatile HPV with an immune checkpoint inhibitor (ICI). Data from the Triple-therapy regimen showed further improvements over both the two-drug regimen and Keytruda alone in both naïve and refractory patients.

After consulting with oncologists, PDS amended the trial to add a third Triple-combination arm. We believe this VERSATILE-003 Plus design has several advantages over the two-arm trial, including possible NDAs for both drugs from a single trial. There were several points that should make this trial a first choice for oncologists to enroll their patients over other trials testing Keytruda combinations.

The Phase 3 trial, renamed "VERSAMUNE-003 Plus", will treat patients with either Versamune HPV with Keytruda, Versamune HPV and PDS01ADC with Keytruda, or Keytruda alone. These three-arms are intended to show the activity of each drug alone or in combination. An interim analysis has been prospectively included to allow early approval, if justified.

Additional Pipeline Products Continue To Advance. Versamune is the proprietary antigen-carrier technology that can be customized to simulate an immune response against cells that display that specific antigen. Versamune HPV is the most advanced product made with this technology platform.

An IND for clinical trials planned during FY2024 for PDS0103, a Versamune molecule that delivers the MUC-1 (mucin-1) antigen commonly found in breast, lung, ovarian, and other cancers. Additional preclinical products using the Versamune technology as a carrier for other cancers and infectious diseases have been tested in preclinical studies.

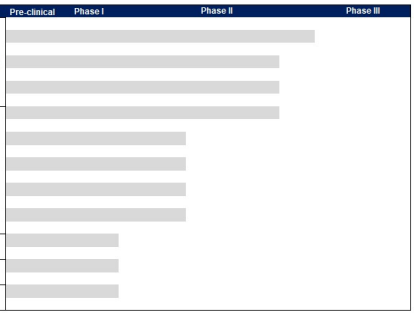
Versamune HPV and PDS01ADC are currently in additional Phase 2 trials with other regimens and tumor types. Data updates from these Investigator-initiated trials (ITTs) trials are expected to report data during 2H24. The Phase 2 ImmunoCerv trial is testing Versamune HPV with radiotherapy for locally advanced cervical cancer at MD Anderson Cancer Center. The trial previously reported interim results with an update expected later in 2024. A second neoadjuvant trial is testing Versamune HPV in locally advanced oropharyngeal cancer (OPSCC) at the Mayo Clinic.

Conclusion. By amending the Phase 3 trial design to the three-arm study, two drugs will be tested in a single trial that could lead to approval for both drugs sooner and with lower trial costs. Although this delayed the expected start of Phase 3, it was a significant step that we see as an improvement that should resolve some of the uncertainty around the Phase 3 trials. The trial could potentially give the best clinical results in HNSCC to date and aligns the long-term interests of both patients and shareholders.

We continue to believe that both Versamune HPV and PDS01ADC can make significant contributions to overall survival and patient outcomes. We are reiterating our Outperform rating and $17 price target.

Exhibit 1. PDS Pipeline.

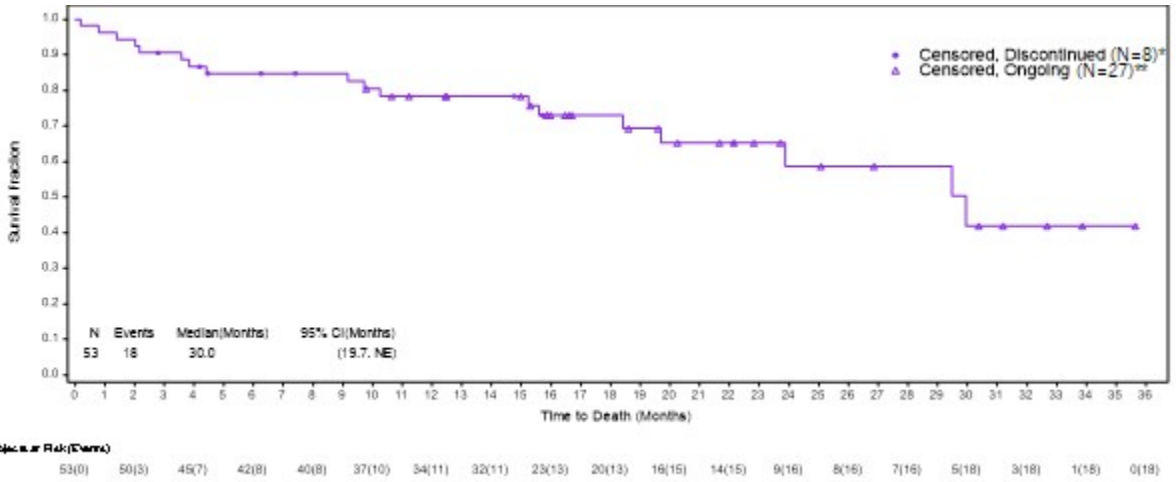
Product	Target Antigen	Trial Name	Indication	Combination	Partner
PDS0101	HPV	VERSATILE-002/003	Head and Neck cancer (SCC)	Keytruda	Merck
		IMMUNCERV	Cervical cancer (first line)	Chemotherapy/radiation	MD Anderson
		Neoadjuvant	Oropharngeal cancer (premetastatic)	Keytruda	Mayo Clinic
PDS01ADC with PDS0101 (previously PDS0301)	HPV	Triple Combination	HPV+ tumors	Checkpoint inhibitor	NCI/NIH
			Advanced Kaposi's sarcoma	Monotherapy	NCI/NIH
			Metastatic prostate cancer	Docetaxal	NCI/NIH
			Localized prostate cancer	Radiation	NCI/NIH
			HPV-related colon and small bowel cancer	HDAC inhibitor	NCI/NIH
PDS0102	TARP		TARP-positve AML, prostate, and breast	TBD	NCI/NIH
PDS0103	MUC-1		MUC-1 positive breast, lung, ovarian cancer	TBD	NCI/NIH
PDS0104	TARP2		Melanoma	TBD	



Source: PDS Biotechnology Corp.

Updated VERSATILE-002 Phase 2 Data Shows Best Survival. In June 2024, PDS updated the results of the Phase 2 VERSATILE-002 study through an analysis point in May 2024. Median overall survival (mOS) is still 30.0 months and remains consistent with the data analysis from November 30, 2023. Some patients are reaching the 3-year survival milestone, with 27 out of the 53 patients alive. The full trial population includes 18 that have died, 6 that have withdrawn consent for further follow-up, and 2 that have been lost to follow-up. This is a substantial improvement over the 17.9 months survival from Keytruda monotherapy seen in a recent study. The full analysis of the May 2024 evaluation point is expected during 2H2024.

Exhibit 2. Survival Curve for VERSATILE-002. The Kaplan-Meier analysis from the May 17, 2024, data evaluation point shows survival of 30.0 months after treatment with Versamune HPV and Keytruda. The lower limit of the 95% confidence interval is 19.7 months, and the upper limit is not yet estimable, as 27 out of 53 patients continue to be followed for survival.



Source: PDS Biotechnology Corp.

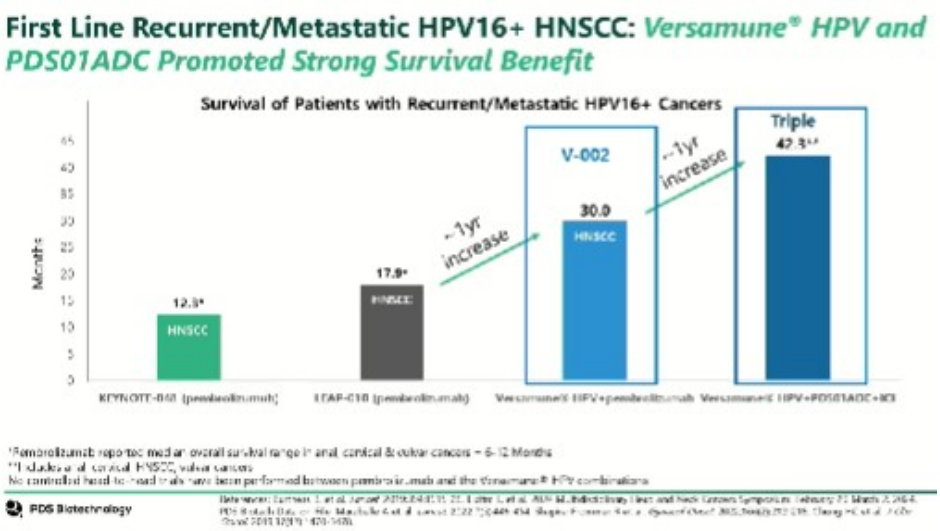
Versamune HPV Continues To Show Efficacy. The Phase 2 VERSATILE-002 data presentations have shown consistent improvements in several clinical measures of efficacy including overall survival (OS), progression free survival (PFS), and response rates (RR). Other measures, including the percentage of patients remaining alive at different time points, have also shown meaningful improvements over previous studies.

Following the ASCO data presentation in June 2023, PDS held an End-of-Phase 2 meeting with the FDA to discuss requirements for Phase 3 and a Biologics Licensing Application (BLA). Based on the strength of the response and overall survival, the company was encouraged to accelerate its plans to move to Phase 3.

Following this meeting, PDS designed the double-blind VERSATILE-003 enrolling larger patient numbers against an active control. The trial design was based on the treatment regimen in the Phase 2 trial, with only a single variable between the two groups and increased patient enrollment to provide the statistical significance required for approval. This has been a common development strategy for Phase 3 data leading to a BLA application.

The trial had a treatment arm testing Versamune HPV with Keytruda against a control arm with Keytruda alone in ICI-naïve patients. This patient group had shown overall survival of 30.0 months, exceeding the 17.9-months survival for Keytruda monotherapy in the best study available at that time. The primary endpoint was overall survival, consistent with other Phase 3 trials that recently led to product approvals. Progression-free survival, response rates, and other clinical measures that characterize the response became secondary endpoints.

Exhibit 3. The Phase 2 Versamune HPV Trials Show Best HNSCC Overall Survival To Date. The Keynote-048 trial testing Keytruda showed an improvement of 12.3 months. The LEAP-010 study testing EGFR/PD-1 (lenvatinib/pembrolizumab) inhibitors in R/M HNSCC combination showed 17.9 months for its Keytruda monotherapy arm. Overall survival in the VERSATILE-002 was 30.0 months and 42.3 months in the Triple-combination study.

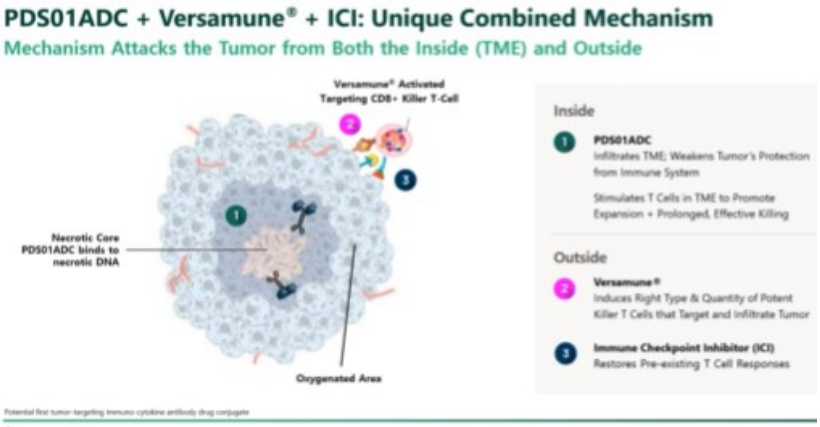


Source: PDS Biotechnology Corp.

Triple-Combination Data Led To Changes In Phase 3 Design

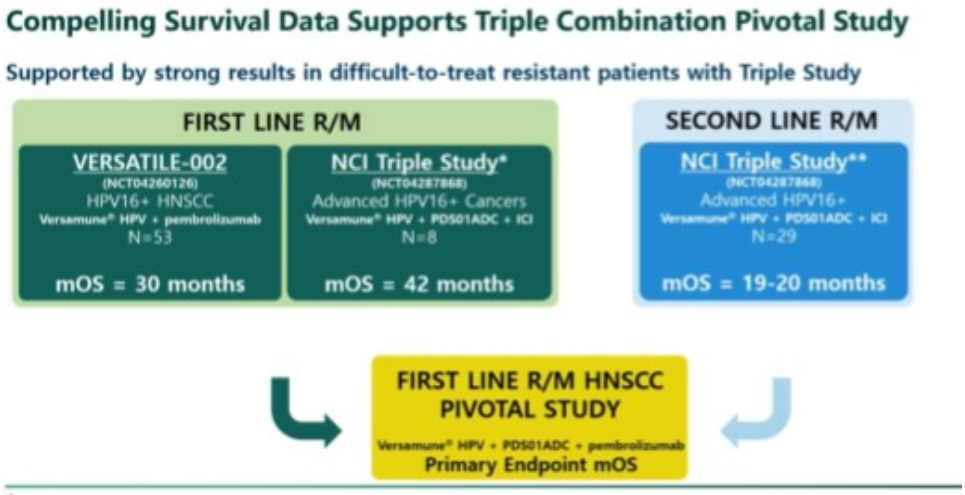
As the Phase 3 trial was in the planning stages, additional data from the Phase 2 Triple-combination therapy regimen (Versamune HPV, PDS01ADC, and a checkpoint inhibitor) became available. The trial showed improved survival in patients with recurrent/metastatic disease (R/M HNSCC) that had not received previous therapy with an immune checkpoint inhibitor (ICI-treatment naïve) as well as patients that had failed treatment with checkpoint inhibitors (ICI-refractory). The ICI naïve patients reached 42 months survival, while the ICI-refractory patients showed overall survival of 19 to 20 months survival compared with 3 to 4 months for Keytruda alone. This survival data in naïve patients exceeded any other reported trial to date, while providing significant survival for the refractory patients that had no effective treatments remaining.

Exhibit 4. Schematic Illustration of Triple Therapy Combination. Mechanism of Action For Versatile HPV and PDS01 ADC. The two mechanisms of action combine to stimulate anti-HPV16 T-cells and increase the immune cell populations.



Source: PDS Biotechnology Corp.

Exhibit 5. Phase 2 Showed Improved Survival Over Keytruda Alone. VERSATILE-002 and Triple-combination study tested the double and triple regimens in both first line and second line relapsing/metastatic head and neck squamous cell carcinoma (R/M HNSCC).



Source: PDS Biotechnology Corp.

The Triplet Regimen Was Preferred By Oncologists. PDS management began discussing the Phase 2 data and plans for Phase 3 plans with clinical oncologists and advisors. The doctors were encouraged by the Phase 2 data but said they would prefer to use the Triple-combination for all their patients as first-line therapy. While both Phase 2 studies showed significant improvements over published trials, the Triple-combination data exceeding any reported overall survival data. This included refractory patients with advanced disease patients that are most difficult-to-treat.

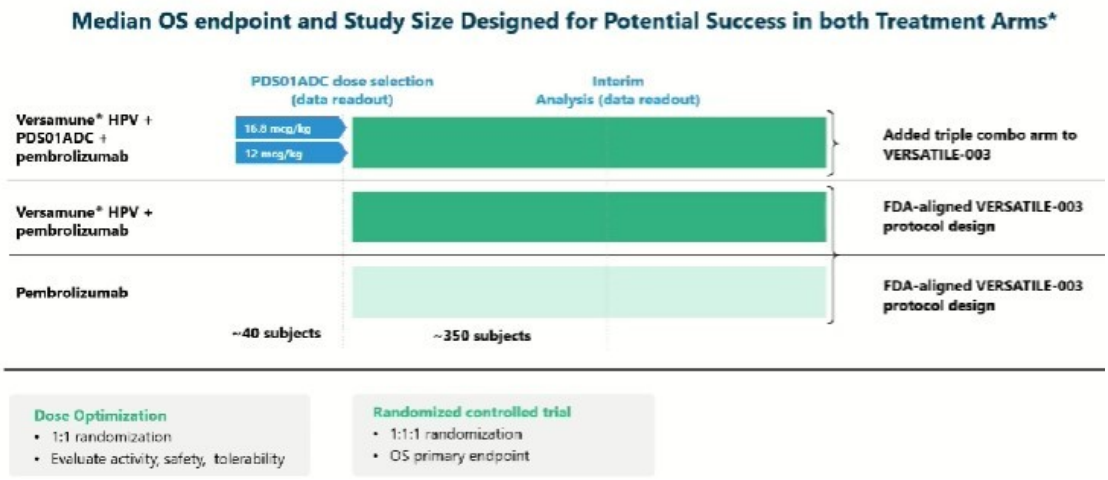
In these conversations, the Oncologists explained why they would want to use the Triple-combination in either naïve or refractory patients as first-line treatment. The lack of additional toxicities from the two or three drug combinations made it safe to use without having to waiting for relapse or metastasis with approved chemotherapy regimens. Although it used two unapproved drugs, the mechanism of action and biomarker data supported the contributions of each drug to the responses seen. They also gave other insights from their clinical practice that would help enrollment in the trial:

- **Competition For Patients.** The oncologists pointed out that there are other clinical trials testing drugs in combination with Keytruda, each showing some improvement. With many trials to choose from, doctors enroll patients in the ones that are likely to produce the best results, balancing expected efficacy and side effects. This favors the VERSAMUNE-003 Plus trial over others.

- **No Cumulative Toxicities.** Combinations of chemotherapy drugs can give additive or synergistic side effects that make effective treatments too toxic for patients to tolerate. Versamune HPV and PDS01ADC act by directing the immune system to respond to the tumor antigens, with actions that are highly specific to the HPV tumor microenvironment and cause few off-target side effects. In some cases, the high specificity reduced some of the autoimmune side effects expected with checkpoint inhibitors.

- **Higher Chance of Receiving Experimental Therapy Is What Patients Prefer.** When asked to participate in clinical trials where the course of disease is known, patients often see the experimental drug as a chance for a better outcome. Many express preferences for trials with a higher than 50% chance of receiving the test drug over the control group. The three-arm design gives a 2-in-3 chance rather than 1-in-2, which is more likely to result in patient willingness to enroll. This was cited as a factor favoring patient participation and faster enrollment.

Exhibit 6. The New "VERSATILE-003 Plus" Trial Design. The new trial is designed to test the doublet regimen seen in the Phase 2 VERSATILE-002 trial in one arm, the Triple-combination therapy in the second arm, and Keytruda alone in a third active-control arm. A dose selection stage will test the Triple-combination in about 40 patients to select the optimal dose. Patients will be randomized 1:1:1, with about 115 to 120 patients in each group. The primary endpoint is overall survival (OS). PDS expects to hold a meeting with the FDA in July 2024 to receive feedback and guidance on the trial.



Source: PDS Biotechnology Corp.

Overview: PDS' Strategy In Head and Neck Cancer

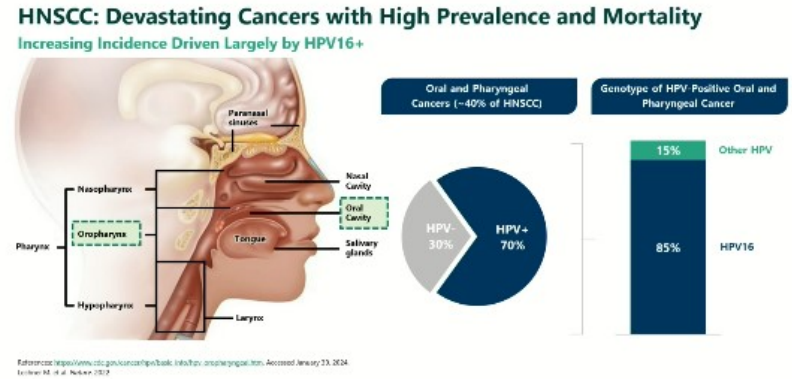
Head and neck squamous cell carcinomas typically arise from the mucosal epithelial cells in the mouth and neck. Cancers in the oral cavity and larynx are generally associated with alcohol and tobacco use, while those in the pharynx are often attributed to infection with human papillomavirus (HPV), primarily HPV16. This is attributed to the viral impairment of the T-cell response that normally kills cancer cells, allowing the tumors to grow.

Head and neck carcinoma is the seventh most common cancer, with 1 million deaths worldwide. Of these, oropharyngeal cancer is about 40% of all HNC. HPV infection increases cancer risk by and estimated 15-fold to 200-fold, with about 80% to 90% of the cases testing HPV16+.

Although HPV vaccines have been available since 2006, the time from initial infection to diagnosis can be 20 years or more. In addition, vaccination rates in the US are relatively low and incidence of HPV-related cancers is rising. HPV-related cancer incidence is expected to increase through the mid-2030s before it peaks then decreases. Thus, HPV-related cancers will remain an unmet medical need for many years.

HPV Status Influences HNSCC Outcomes. HNSCC tumors are classified as HPV-negative and HPV-positive. Patients with HPV-positive oropharyngeal tumors have a better prognosis and higher chance of complete cure than those with HPV-negative tumors receiving the same treatment.

Exhibit 7. HNSCC Is A Cancer of The Oral Cavity. Squamous Cell Carcinoma affects the mouth (tongue, lips, glands, pharynx) and oral cavity. HPV16+ tumors are about 30% of the overall incidence, and about 85% of those found in the oropharynx.



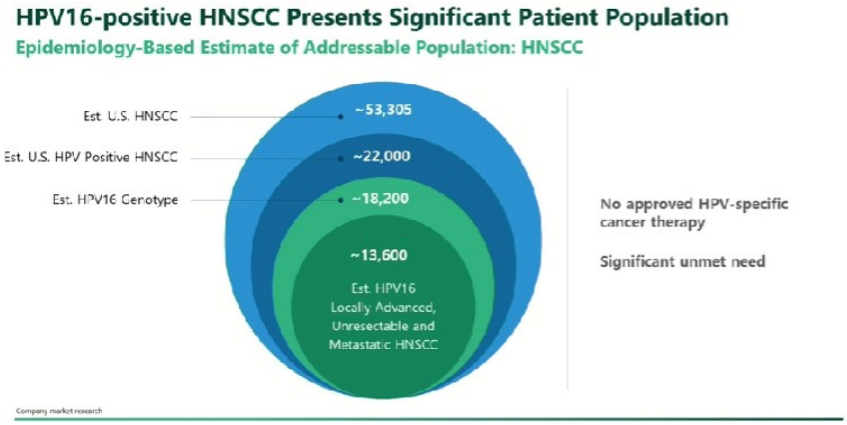
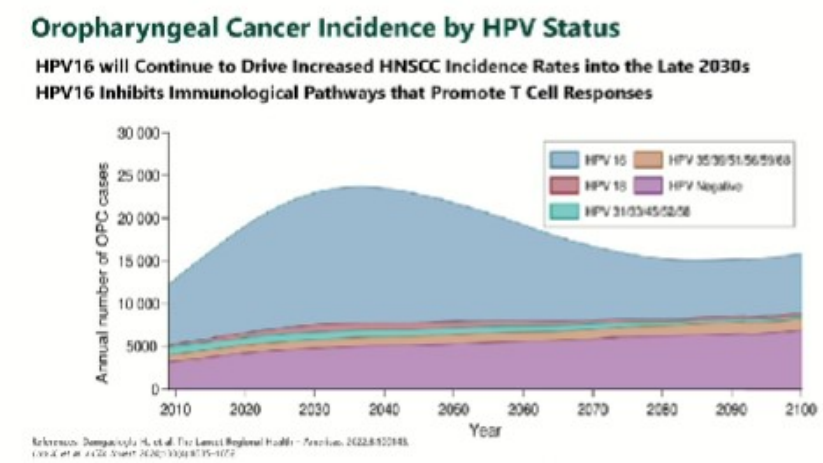


Exhibit 8. Vaccination against HPV infection is highly effective when given between the ages of 13 to 17, but vaccination rates have been relatively low in the US. While incidence of HNSCC from smoking is decreasing, the incidence from HPV infection is increasing and is projected to increase through the mid-2030s.



Sources: PDS Biotechnology Corp.

PDS Has Developed Drugs That Address The Causes Of Immunotherapy Failure

Head and neck cancer has historically been treated with a combination of surgery, radiation, and chemotherapy. In recent years, two anti-PD-1 immune checkpoint inhibitors, Keytruda (pembrolizumab, from Merck) and Opdivo (nivolumab, Bristol-Meyers), were approved and became the standard of care. These act by blocking the PD-1/PD-L1 interaction, allowing the immune system to recognize tumor cells as harmful and kill them.

When introduced, the response rates for the checkpoint inhibitors were around 20%-30%, with a median survival of around 12.3 months. The LEAP-010 study (2023) showed a median survival for Keytruda monotherapy of 17.9 months. These were improvements over the median 2 to 3 months expected survival from cytotoxic chemotherapy.

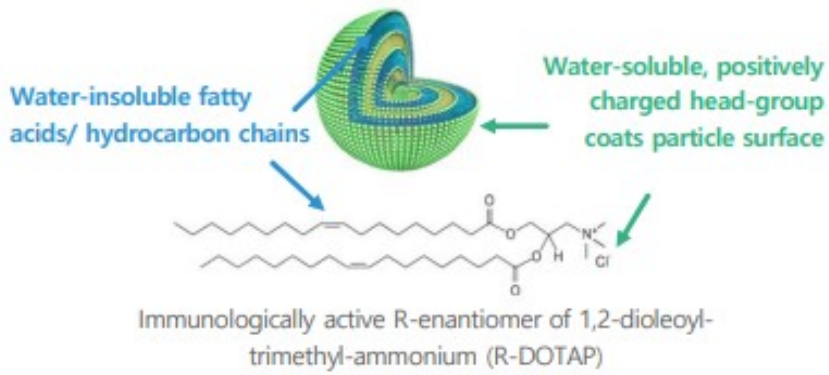
The PD-1 checkpoint inhibitors have improved patient survival but have low response rates with side effects that are difficult for patients to tolerate. One of the challenges has been to improve response rates and overall survival without increasing the toxicity. Research on improving response rates has identified several factors, including immune biomarkers and immune status of cancer cells. Findings have shown immunotherapies fail for two main reasons:

- **Lack of T-cells.** Tumors that lack sufficient numbers of immune cells to carry out the killing step known as “immunologically cold tumors” or “immune deserts”. Attempts to increase the immune cell population, “turning cold tumors hot”, has been one of the strategies to improve the response rates. The tumor can also suppress the immune system, reducing the population and activity of immune cells available.
- **Immune-Excluded Tumors.** Many tumors have an outer stroma (layer) that protects the tumor cells and isolates the tumor microenvironment (TME). This prevents circulating immune cells from penetrating the tumor, so the immune system cannot generate the right type or quantity of effective tumor infiltrating lymphocytes (TILs) inside the tumor.

PDS Triple Therapy Attacks From Outside and Inside To Overcome These Problems

Versatile HPV Was Designed To Prime The Immune System Against HPV16. Versamune HPV is the lead drug produced by PDS’s Versamune technology platform. Versamune HPV uses a lipid nanoparticle to carry the HPV16 antigen to the dendritic cells. These antigen-presenting cells take up the particle, activating the pathways in the lymph nodes that produce CD4+ helper cells, CD8+ killer cells, and cytokines that magnify the immune response against the tumor.

Exhibit 9. Versamune Technology For Antigen Delivery. The Versamune technology uses a proprietary lipid nanoparticle and T-cell activating carrier with a positive charge to facilitate uptake by the dendritic (antigen presenting) cells. This starts the pathways of T-cell production to target the tumor.



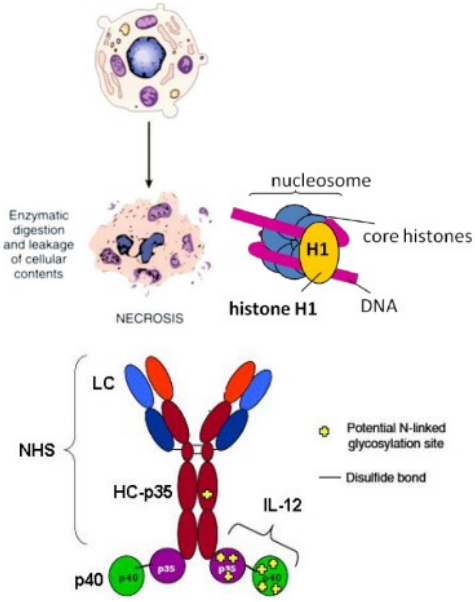
Source: PDS Biotechnology Corp.

PDS01ADC Was Developed To Stimulate An Immune Response Inside The Tumor. Scientists at the National Cancer Institute developed the drug now known as PDS0101ADC and conducted the Phase 2 trial (known as the Triplet-combination or NCI trial).

PDS01ADC is a cytokine fusion protein that was modified to deliver IL-12. It contains an antibody domain that targets tumor cell DNA, with IL-12 fused to IgG1 heavy chains. The antibody portion binds to the necrotic DNA released from dead and dying HPV16+ cancer cells, while the IL-12 portion remains bound and does not get released into the systemic circulation. This signals the immune response within the tumor microenvironment, stimulating increases the population of tumor-specific T-cells inside the tumor.

PDS01ADC infiltration results in T-cell proliferation in the TME to enable prolonged and effective killing. Since the Il-12 remains bound to the antibody portion of the molecule, it is not released to the circulation in an active form, avoiding the systemic toxicities seen in previous attempts to use IL-12 to improve the immune response with checkpoint inhibitors. PDS01ADC also downregulates immune suppressors to weaken the tumor's response against the immune system. This combination of targeting and immune stimulation overcomes the tumor defense mechanisms.

Exhibit 10. PDS01ADC Is a Fusion Molecule Derived From An IgG1 Antibody and IL-12. Interleukin-12 (Il-12) is a signaling molecule secreted by white blood cells (mostly dendritic cells, macrophages, neutrophils, helper T-cells, and B-cells). It is released after antigens are detected activate to activate the immune response and mediate the natural killer cell and CD8+ cytotoxic T-cell activity. The composition of PDS01ADC overcomes problems with delivery to the tumor and systemic toxicity seen with previous attempts to improve checkpoint inhibitor efficacy with Il-12.



Source: PDS Biotechnology Corp.

Funding: The company's cash balance was $66.6 million on March 31, sufficient to fund operations other than the Phase 3 trial through the end of 2025 without additional financing. To fund Phase 3, the company would only say that "all options are on the table", which we interpret to include partnerships, collaborations, and capital raises.

Conclusion. By amending its Phase 3 trial design to the three-arm study, the study will test its two drugs in a single trial that could lead to approval for both sooner and with lower trial costs. Although this delayed the expected start of Phase 3, we believe it is a better design. We continue to believe that both Versamune HPV and PDS01ADC can make significant contributions to overall survival and patient outcomes. Although this has delayed the start of the trial, we believe the new trial could lead to approval of both drugs. We are reiterating our Outperform rating and $17 price target.

Company Profile

COMPANY DESCRIPTION

PDS Biotechnology is a clinical stage immuno-oncology company developing immunotherapies for the treatment of cancer. The company's lead product, PDS0101 (Versamune-HPV) is a proprietary immunotherapy for the treatment of human cancers associated with the human papillomavirus (HPV) including head and neck cancer, anal cancer, as well as cervical, penile, vaginal and vulvar cancers.

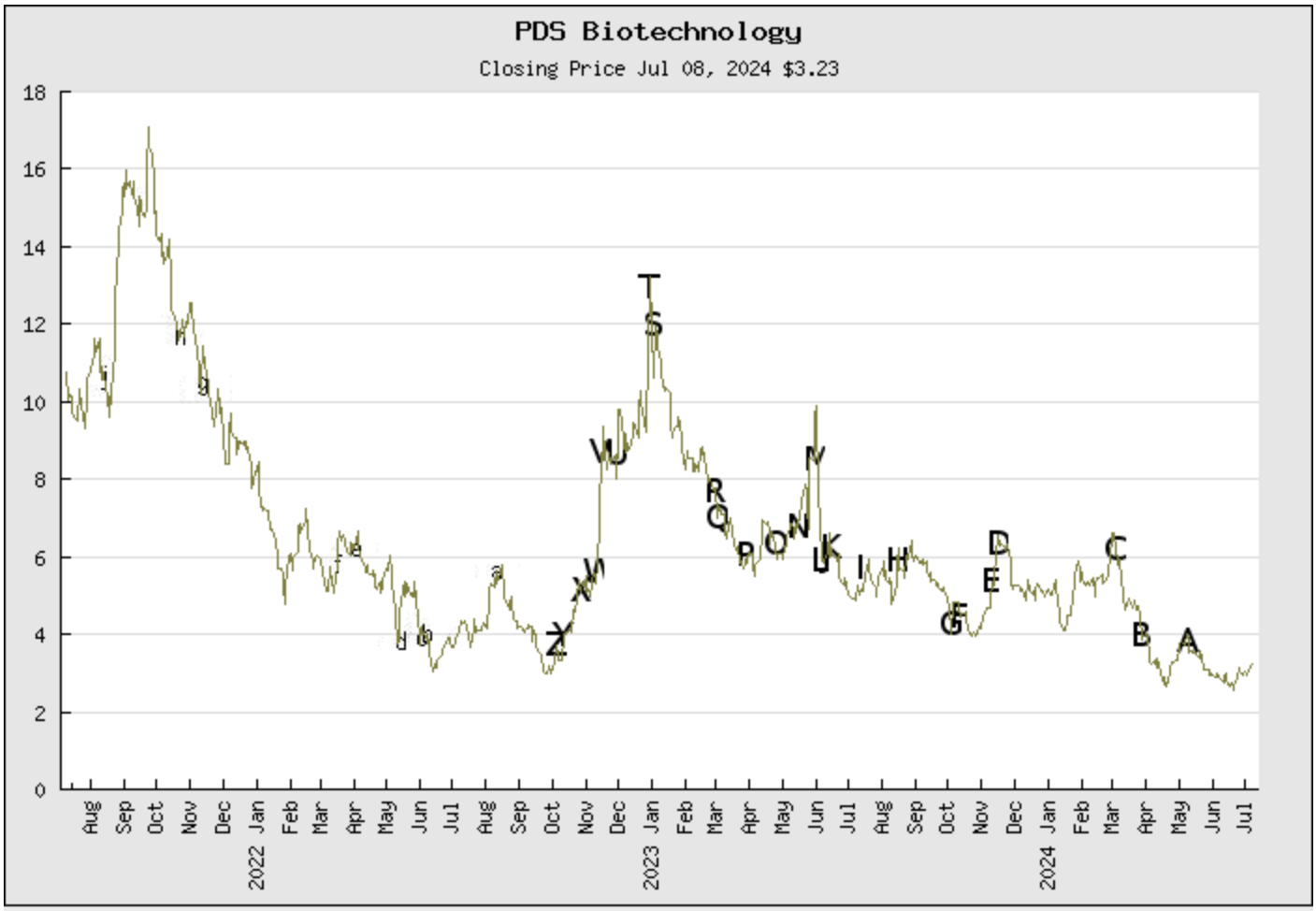
Fundamental Analysis - 4.0/5.0 Checks.

PDS Biotechnology has lead drug, Versamune-HPV, in development for treatment of HPV-associated cancer, representing a large commercial opportunity. Based on our analysis of results from experimental models and early clinical trials, we believe Versamune-HPV has the potential to become an effective cancer treatment. PDS currently relies on investments from institutional and retail investors to fund its clinical programs. This poses financial risks for the Company as there are no guarantees that management will be able to raise sufficient capital to complete clinical development and commercialize its products.

Valuation Summary

We value PDS Biotechnology based on our projected revenues and discounted earnings for PDS0101. We anticipate introduction in 2026 in head and neck cancer, with some use in cervical cancer and other tumor use following in 2027-28. We discount revenues by 50% in our earnings models, then applying a discount rate of 30% to our FY2027 estimate of $6.06 per share and a multiple of 15X, our price target is $17 per share.

Risks include: Experimental therapeutic product risk, development timeline risk, financing risk, competitive risk, intellectual property risk.



A - 05/09/2024 Outperform Target $17.00 Current $3.83
B - 03/28/2024 Outperform Target $17.00 Current $3.96
C - 03/04/2024 Outperform Target $17.00 Current $6.17
D - 11/15/2023 Outperform Target $17.00 Current $6.32
E - 11/10/2023 Outperform Target $17.00 Current $5.34
F - 10/12/2023 Outperform Target $17.00 Current $4.45
G - 10/04/2023 Outperform Target $17.00 Current $4.23
H - 08/15/2023 Outperform Target $17.00 Current $5.88
I - 07/18/2023 Outperform Target $17.00 Current $5.71
J - 06/16/2023 Outperform Target $17.00 Current $6.03
K - 06/15/2023 Outperform Target $17.00 Current $6.22
L - 06/07/2023 Outperform Target $17.00 Current $5.91
M - 05/30/2023 Outperform Target $17.00 Current $8.47
N - 05/16/2023 Outperform Target $17.00 Current $6.77
O - 04/24/2023 Outperform Target $17.00 Current $6.33
P - 03/29/2023 Outperform Target $19.00 Current $6.02
Q - 03/02/2023 Outperform Target $19.00 Current $7.02
R - 02/28/2023 Outperform Target $19.00 Current $7.65
S - 01/04/2023 Outperform Target $19.00 Current $11.99
T - 12/29/2022 Outperform Target $19.00 Current $12.92
U - 11/28/2022 Outperform Target $19.00 Current $8.63
V - 11/15/2022 Outperform Target $10.00 Current $8.68
W - 11/08/2022 Outperform Target $10.00 Current $5.58
X - 10/27/2022 Outperform Target $10.00 Current $5.11
Y - 10/12/2022 Outperform Target $10.00 Current $3.97
Z - 10/04/2022 Outperform Target $10.00 Current $3.70
a - 08/10/2022 Outperform Target $22.00 Current $5.64
b - 06/08/2022 Outperform Target $22.00 Current $4.00
c - 05/31/2022 Outperform Target $22.00 Current $3.92
d - 05/12/2022 Outperform Target $22.00 Current $3.83
e - 04/01/2022 Outperform Target $22.00 Current $6.22
f - 03/16/2022 Outperform Target $22.00 Current $5.81
g - 11/11/2021 Outperform Target $22.00 Current $10.50
h - 10/22/2021 Outperform Target $22.00 Current $11.66
i - 09/13/2021 Outperform Target $22.00 Current $14.99
j - 08/13/2021 Outperform Target $17.00 Current $10.65

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or under-served needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	89%	22%
Market Perform: potential return is -15% to 15% of the current price	11%	4%
Underperform: potential return is >15% below the current price	0%	0%

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Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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