PDS Biotechnology

Oct 07, 2024

Healthcare

PDSB

NASDAQ

Rating

Outperform

Unchanged

Current Price

$3.71

Target Price

$17.00

Market Capitalization
136.6M

Shares Outstanding
36.8M

Float
33M

Institutional Holdings
12%

12-Month Low/High
$2.53/$6.85

Average 90-Day Volume
311920

Fiscal Year End
12/31/2024

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	2024E	2025E
Q1	(0.32)A	(0.30)A	(0.37)E
Q2	(0.37)A	(0.23)A	(0.37)E
Q3	(0.35)A	(0.28)E	(0.39)E
Q4	(0.34)A	(0.34)E	(0.41)E
	(1.38)A	(1.38)E	(1.54)E

Clinical Trial in Cervical Cancer Shows Improved Survival and Supports Use In Other Tumors

Interim Data From Phase 2 Cervical Cancer Trial Presented. An interim analysis from the Phase 2 ImmunoCerv Trial in locally advanced cervical cancer was presented at the American Society For Radiation Oncology (ASTRO) annual meeting on October 1, 2024. Overall survival (OS) and progression free survival (PFS) showed clinically meaningful improvements over published studies. We believe this supports the efficacy of Versamune HPV in cervical cancer as well as other HPV16+ tumors in other tissues.

Study Design. The ImmunoCerv study was an investigator-initiated trial (ITT) conducted at MD Anderson Cancer Center in Houston, Texas. The study enrolled 17 patients with newly diagnosed high-risk HPV-related cervical tumors at least 5 cm in size. Patients received up to 5 doses of Versamune HPV along with standard of care chemotherapy and radiation.

Study Results. All of the patients in the data presentation received at least 2 doses of Versamune. Median follow-up was 19 months. Out of the 17 patients evaluated, overall survival at 36 months for the 8 patients that received all five scheduled doses (OS) was 100%. Overall survival for the full 17 patients was 84.4%. This compares with 36-month OS in published studies of about 64%.

PFS and CMR. Progression free survival (PFS) for the 8 patients that received all 5 doses was 100% and 74.9% for all 17 patients and compares with PFS in published data of about 61%. Complete metabolic response (CMR) was reached in 15 out of 17 (88%).

Conclusion. The ImmunoCerv interim data shows improvements in survival in HPV16-related cervical cancer. This supports our opinion that Versamune may prove effective against HPV16+ tumors in any tissue. We look forward interim data from the neoadjuvant trial testing Versamune at the Mayo Clinic, as wells as to the start of Phase 3 VERSATILE-003 testing Versamune in head and neck cancer. The three-armed Phase 3 trial is designed to test Versamune with pembrolizumab, Versamune and PDS01ADC with pembrolizumab, and an active control group receiving pembrolizumab alone. We are reiterating our Outperform rating and $17 price target.

Equity Research

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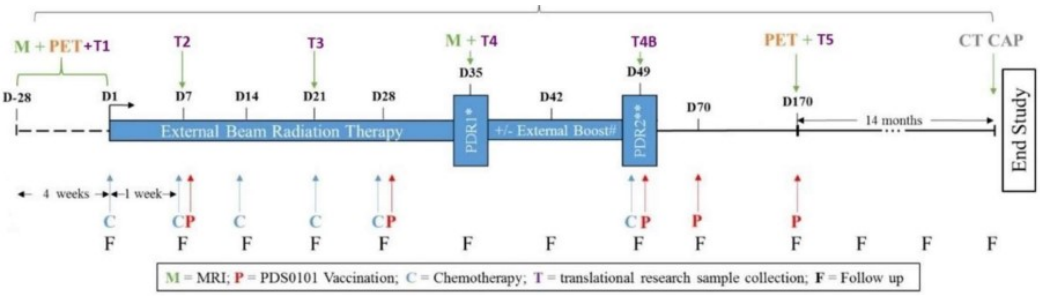
Refer to the last two pages for Analyst Certification & Disclosures

PDS Biotechnology (PDSB) | Current Price: $3.71 | Outperform | Oct 07, 2024

Summary. Data from the Phase 2 ImmunoCerv Trial in locally advanced cervical cancer was presented at the American Society For Radiation Oncology (ASTRO) annual meeting on October 1, 2024. The data shows overall survival (OS) and progression free survival (PFS) that are clinically meaningful improvements over the rates seen published studies. We believe this supports the efficacy of Versamune HPV in cervical cancer as well as other HPV16+ tumors.

Study Design. The ImmunoCerv study is an investigator-initiated trial (ITT) conducted at MD Anderson Cancer Center in Houston, Texas. The study enrolled 17 patients with newly diagnosed high-risk HPV-related cervical tumors at least 5 cm in size. Patients received up to 5 doses of Versamune HPV along with standard of care chemotherapy and radiation.

Exhibit 1. ImmunoCerv Trial Design. Patients received up to five doses of Versamune HPV with chemotherapy and radiation with follow-up evaluations at scheduled intervals over the course of the study.



Source: PDS Biotech Corp.

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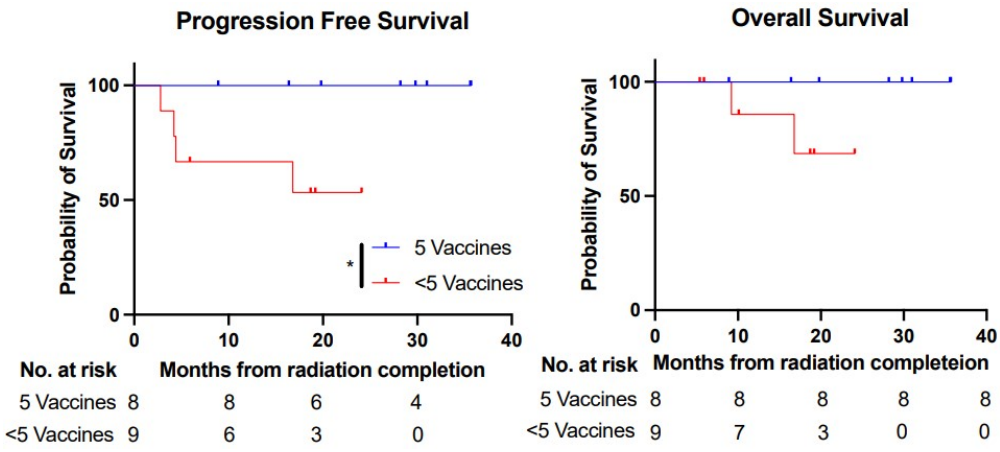
Progression free survival (PFS) for the eight patients that received all five doses was 100% and 74.9% for all 17 patients. PFS in published data is about 61%. Complete metabolic response (CMR) was reached in 15 out of 17 (88%).

Safety and Tolerability. The most common adverse event was injection site reaction in 12 out of 17 (71%) patients. Grade 3 or higher (acute) adverse reactions were seen in eight patients (47%), close the expected rate of Grade 3 or higher events seen in standard-of-care chemoradiation therapies.

Exhibit 2. 36-month PFS and OS Were 100% In Patients That Received All 5 Doses. All of the patients received at least two Versamune treatments, but the eight patients that received the full course of five Versamune treatments showed both Progression Free Survival (PFS) and Overall Survival (OS) of 100% in the study.



Source: PDS Biotech Corp.

Conclusion. The ImmunoCerv interim data shows survival improvements in HPV16-related cervical cancer. This supports our opinion that Versamune may prove effective against HPV16+ tumors in any tissue type. An Investigator-Initiated trial testing Versamune HPV as an adjuvant (given at the time of surgery) in locally advanced oropharyngeal cancer (OPSCC) is underway at the Mayo Clinic.

We look forward to the start of Phase 3 VERSATILE-003 testing Versamune in head and neck cancer around year-end. The three-armed trial is designed to test Versamune with pembrolizumab, Versamune and PDS01ADC with pembrolizumab, and an active control group receiving pembrolizumab alone. 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.

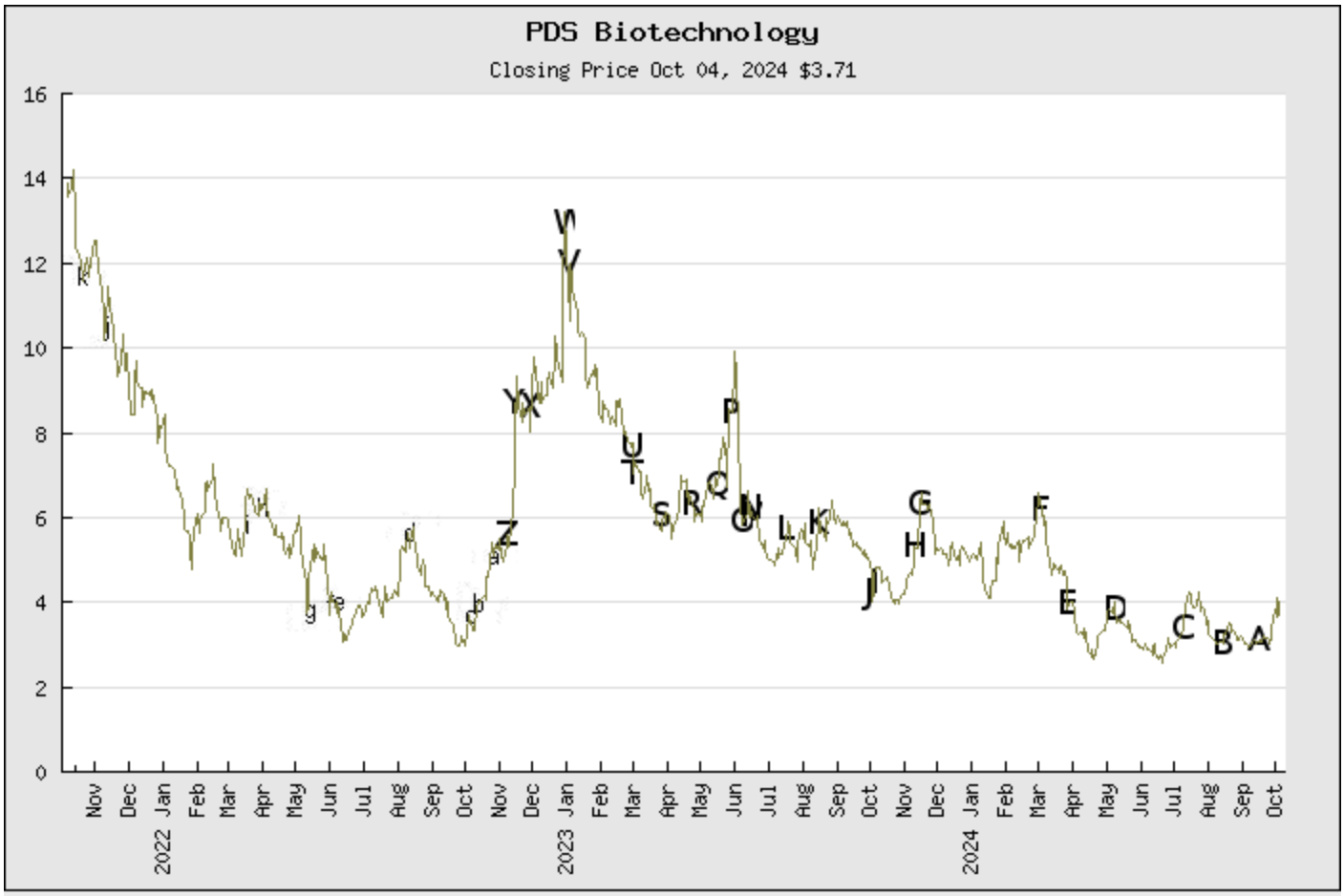
Fundamental Analysis - 4.0/5.0 Checks.

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 - 09/17/2024 Outperform Target $17.00 Current $3.12
B - 08/14/2024 Outperform Target $17.00 Current $3.02
C - 07/09/2024 Outperform Target $17.00 Current $3.37
D - 05/09/2024 Outperform Target $17.00 Current $3.83
E - 03/28/2024 Outperform Target $17.00 Current $3.96
F - 03/04/2024 Outperform Target $17.00 Current $6.17
G - 11/15/2023 Outperform Target $17.00 Current $6.32
H - 11/10/2023 Outperform Target $17.00 Current $5.34
I - 10/12/2023 Outperform Target $17.00 Current $4.45
J - 10/04/2023 Outperform Target $17.00 Current $4.23
K - 08/15/2023 Outperform Target $17.00 Current $5.88
L - 07/18/2023 Outperform Target $17.00 Current $5.71
M - 06/16/2023 Outperform Target $17.00 Current $6.03
N - 06/15/2023 Outperform Target $17.00 Current $6.22
O - 06/07/2023 Outperform Target $17.00 Current $5.91
P - 05/30/2023 Outperform Target $17.00 Current $8.47
Q - 05/16/2023 Outperform Target $17.00 Current $6.77
R - 04/24/2023 Outperform Target $17.00 Current $6.33
S - 03/29/2023 Outperform Target $19.00 Current $6.02
T - 03/02/2023 Outperform Target $19.00 Current $7.02
U - 02/28/2023 Outperform Target $19.00 Current $7.65
V - 01/04/2023 Outperform Target $19.00 Current $11.99
W - 12/29/2022 Outperform Target $19.00 Current $12.92
X - 11/28/2022 Outperform Target $19.00 Current $8.63
Y - 11/15/2022 Outperform Target $10.00 Current $8.68
Z - 11/08/2022 Outperform Target $10.00 Current $5.58
a - 10/27/2022 Outperform Target $10.00 Current $5.11
b - 10/12/2022 Outperform Target $10.00 Current $3.97
c - 10/04/2022 Outperform Target $10.00 Current $3.70
d - 08/10/2022 Outperform Target $22.00 Current $5.64
e - 06/08/2022 Outperform Target $22.00 Current $4.00
f - 05/31/2022 Outperform Target $22.00 Current $3.92
g - 05/12/2022 Outperform Target $22.00 Current $3.83
h - 04/01/2022 Outperform Target $22.00 Current $6.22
i - 03/16/2022 Outperform Target $22.00 Current $5.81
j - 11/11/2021 Outperform Target $22.00 Current $10.50
k - 10/22/2021 Outperform Target $22.00 Current $11.66

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Noble is not a market maker in the Company.

FUNDAMENTAL ASSESSMENT

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	90%	25%
Market Perform: potential return is -15% to 15% of the current price	10%	3%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

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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Report ID: 27015