Biotechnology

PSTV - NASDAQ January 18, 2023

Intraday Price 1/18/23	**$0.45**
Rating:	Buy
12-Month Target Price:	$2.00
52-Week Range:	$0.29 - $1.20
Market Cap (M):	15.1
Shares O/S (M):	33.6
Float:	99.6%
Avg. Daily Volume (000):	359.9
Debt (M):	$6.3
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2021A	2022E	2023E
1Q	2,479	3,926A	6,554
2Q	2,575	5,120A	6,839
3Q	3,499	5,167A	7,409
4Q	3,689	5,270	7,694
FY	12,492	19,483	28,498

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Plus Therapeutics, Inc.

Buy

First Patient Dosed in ReSPECT P2b GBM Study

Summary

- **This morning, Plus announced that the first patient has been dosed in the P2b (ReSPECT) dose expansion study evaluating Rhenium Nanoliposome (RNL) in patients with recurrent glioblastoma (GBM).**
- **Imaging data from this patient demonstrates highly targeted radiation exposure, similar to what was seen in the P1/2a ReSPECT GBM study, which was presented at Society for Neuro-Oncology (SNO) meeting (see details).**
- **The P2b will enroll an additional N=~31 patients with small- to medium-sized tumors (20 mL or less). Enrollment is expected to complete in ~24 months. The company is currently working to accelerate enrollment and expand trial sites over 2023.**

Details

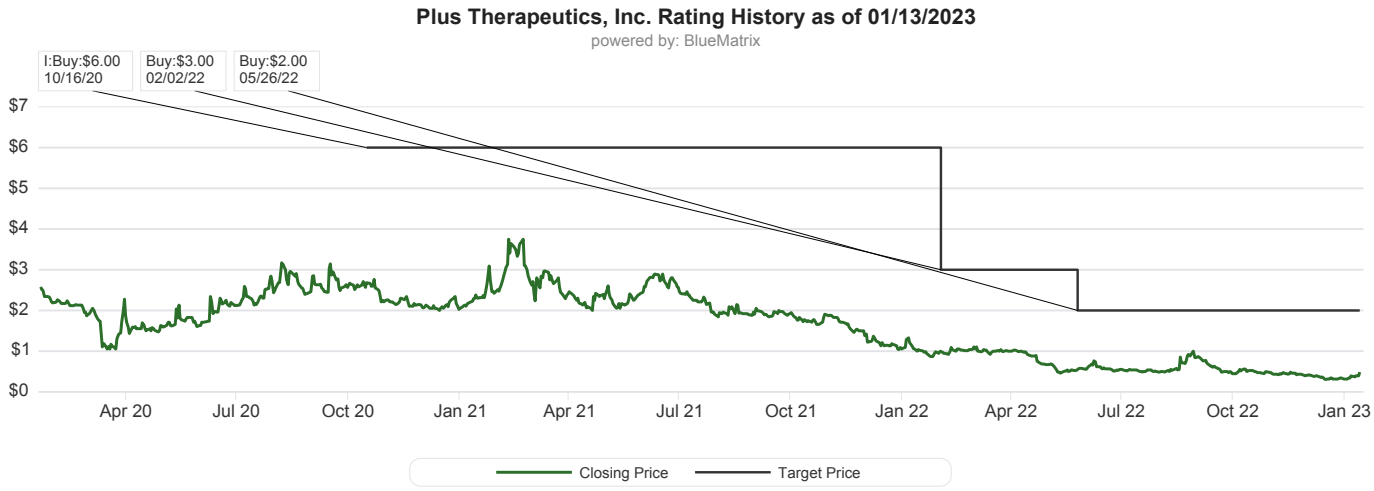
Rhenium Nanoliposome (RNL): volume + dose = better tumor coverage and improved outcomes. RNL is a radioisotope-based therapy administered directly to the brain tumor via convection-enhanced delivery (CED). This technique generates a pressure gradient at the tip of infusion catheters inserted through burr holes into interstitial spaces in the brain, driving flow. Using this technique, the therapeutic agent can bypass the blood-brain barrier. As the therapeutic agent is infused into the extracellular space, extracellular fluid is displaced. The liposomal encapsulation extends its intracranial half-life significantly and decreases the clearance rate from the brain; the drug is retained in the tumor area. In addition, and as important in our view, the use of RNL's gamma emissions allows imaging the isotope using standard nuclear imaging equipment. This gives the physician(s) administering RNL very high precision, and they can actually visualize the tumor area coverage. Safety is another key aspect of therapy. Given its direct placement into the tumor area, the radiation is placed where it is needed and allows for absorbed doses that are much higher than can be achieved with external beam radiation (EBRT).

P2b (ReSPECT) GBM trial design. This P2b trial is designed to evaluate the safety, tolerability, distribution, and efficacy of RNL infused directly into the tumor via convection-enhanced delivery catheters in patients with recurrent or progressive glioblastoma (GBM), disease progression after standard-of-care (SOC) with surgery/chemo/radiation. The P2b is expected to enroll ~N=31 additional patients with small- to medium-sized tumors (20 mL or less). The company expects to enroll these patients over ~24 months. Based on data from the P1/2a (ReSPECT) study, a dose of 22.3 mCi in 8.8mL was recommended for the P2b. Note, this trial is supported by an award from the National Cancer Institute (NCI), part of the US National Institutes of Health (NIH). This morning (1/18), Plus announced that the first patient in the P2b had been dosed. We look forward to updates on the program as the company continues to enroll patients as new sites come online.

Prior P1/2a GBM (ReSPECT) data. The P1/2a (ReSPECT) study was a dose-escalating study in patients with recurrent or progressive GBM, having already been through standard-of-care (SOC) with surgery/chemo/radiation. On 11/19/22, Plus presented data from the study in an oral presentation at the annual Society for Neuro-Oncology (SNO) meeting held November 17-20, 2022, in Tampa, FL. The data came from 24 patients receiving a single dose of RNL in the escalation phase, achieving up to 740 Gray. Among the key findings: between one and four intracranial CED catheters were placed in each patient, and no-dose limiting toxicities were observed with an overall positive safety profile. Importantly, a stat-sig. improvement in overall survival (OS) correlated with the average observed dose and the percentage volume of tumor treated. More specifically, a 100 Gray increase in the absorbed dose correlated with a 35.7% decrease in the risk of death (p=0.003). Further, a 1% increase in tumor volume treated was associated with a 4.5% decrease in the risk of death (p=0.002). Overall, the data highlight RNL's potential to safely prolong survival in patients when a dose of more than 100 Gray is achieved.

Valuation. We model commercialization of Rhenium Nanoliposome (RNL) in 2025 for recurrent glioblastoma. A 75% revenue risk adjustment is factored in based on the stage of development and clinical trial risk. We do not factor in additional RNL programs or potential for pipeline assets. We then apply a 35% discount rate to our FCF, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target of $2.

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 01/17/23
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**86%**	**42%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	**14%**	**58%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**0%**	**0%**
	**See valuation section for company specific relevant indices*		

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

I, Michael Okunewitch, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Plus Therapeutics, Inc.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Plus Therapeutics, Inc. in the next 3 months.

PSTV: For Plus Therapeutics, Inc., we use the BTK (ARCA Biotechnology index) as the relevant index.

Valuation Methods

PSTV: We model commercialization of Rhenium Nanoliposome (RNL) for recurrent glioblastoma. A revenue risk adjustment is factored in based on stage of development and clinical trial risk. We do not factor in additional RNL programs or potential for pipeline assets. A discount rate is then applied to our free cash flow (FCF), discounted EPS, and sum-of-the-parts models which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks

PSTV: Aside from general market and other economic risks, risks particular to our price target and rating for Plus Therapeutics, Inc. include:(1) the regulatory and clinical risk associated with product development; (2) the ability to access capital and the very high likelihood that company will need to raise additional capital, the terms of which may not be favorable based on the outcome of clinical data and other factors, and if the company is unable to raise capital, this may hinder the company's ability to continue operations; (3) the rate and degree of progress of product development; (4) the rate of regulatory approval and timelines to potential commercialization of products; (5) the level of success achieved in clinical trials; (6) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (7) the liquidity and market volatility of the company's equity securities; (8) regulatory and manufacturing requirements and uncertainties; (9) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (10) inability, if product(s) is approved to gain adequate market share;(11) ability of the company to maintain its exchange listing; (12) impact of comprehensive tax reform in the US and Ex-US tax policy; (13) delays related to COVID-19 could impact the company's ability operate and conduct clinical trials; (14) inability to satisfy existing and/or future debt obligations; (15) failure of third-parties to meet contractual obligations, potentially impacting drug development; (16) capital raised via equity financing or convertible debt securities, as well as currently outstanding and possible future warrants and convertible preferred shares, will likely have a dilutive effect for investors.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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