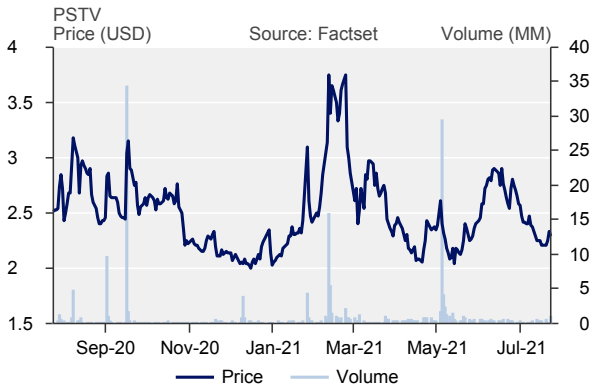
Biotechnology

PSTV - NASDAQ July 23, 2021

Intraday Price 7/23/21	**$2.17**
Rating:	Buy
12-Month Target Price:	$6.00
52-Week Range:	$1.92 - $5.42
Market Cap (M):	22.2
Shares O/S (M):	10.2
Float:	98.7%
Avg. Daily Volume (000):	978.2
Debt (M):	$6.3
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2020A	2021E	2022E
1Q	2,559	2,479A	3,774
2Q	2,537	2,575A	3,939
3Q	1,396	3,052	4,267
4Q	3,395	3,170	4,431
FY	9,887	11,276	16,411
Prior	—	11,737	16,878



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Plus Therapeutics, Inc.

Buy

RNL Platform Making Progress – First Patient in 8th Cohort of Ongoing P1 ReSPECT Trial Dosed

Summary

- **Plus reported 2Q21 results last night with a net loss of ($2.8M) and ended the period with $17.2M in cash on the balance sheet.**
- **The company announced the dosing of the first patient in the 8th cohort of its ongoing P1 ReSPECT dose escalation study evaluating Rhenium Nanoliposome (RNL) in recurrent glioblastoma (rGBM). Twenty-two patients have been enrolled so far across all eight dosing cohorts. No dose-limiting toxicities (DLTs) have been noted so far at absorbed radiation doses of up to 740 Gray, approximately 20X the dose typically received in standard of care (SOC) external beam radiation therapy (EBRT).**
- **Bottom line is the higher dose and higher volumes are not only safe, but most importantly getting maximal disease area coverage. Recall, GBM tumors are not spheres, they are irregular shaped tumors with tentacle-like projections that are often not removed with surgical resection, leading to recurrence. RNL, given its tumor bed coverage which is viewed via imaging, may be reaching those tumor areas that escaped resection and if so, this could potentially improve outcomes; data expected in 4Q21.**

Details

Rhenium Nanoliposome (RNL) – a differentiated approach to treating GBM. Glioblastoma (GBM) is a highly challenging indication to treat, with the majority of patients dying within 15-18 months of diagnosis. SOC comprises surgical resection, radiation therapy, and chemotherapy with alkylating agent temozolomide (TMZ), and has remained largely unchanged for decades. After undergoing frontline therapy, tumor recurrence often takes place for the majority of patients, at which point few options remain. Bevacizumab (beva) is an anti-VEGF monoclonal antibody that is often used in a salvage therapy capacity, in conjunction with chemotherapy. Little survival benefit is provided by these post-frontline therapies, with their benefit largely being palliative.

RNL is a differentiated radionuclide drug-candidate comprising radionuclide Rhenium-186 (Re-186) and a liposomal carrier. Using convection enhanced delivery (CED), RNL is delivered directly to the site of the tumor through stereotactically placed catheters. The direct administration of the therapeutic candidate should enable the delivery of substantially higher radiation doses, while circumventing the blood-brain barrier (BBB), a common impediment to the development of effective therapies in the GBM space.

First patient dosed in the 8th cohort of the ongoing Phase 1 ReSPECT dose escalation study. The Phase 1 study is expected to enroll N=55 patients, of whom 22 have been enrolled and treated so far. Patients enrolled in the study will have recurrent or progressive glioma that has been previously treated with SOC surgery, radiation, and chemotherapy. The study comprises two parts: part 1 and part 2. In part 1, the distribution, safety, and tolerability of RNL administered to patients with recurrent or progressive malignant glioma will be evaluated via an open-label, dose escalation study. The study will utilize a modified Fibonacci dose escalation paradigm followed by expansion at the maximum tolerated dose (MTD) to evaluate efficacy. Part 2 will be a non-blinded, single-arm prospective study with overall survival as the primary endpoint in patients experiencing a single recurrence of disease following SOC multimodal therapy and who are bevacizumab-naive. Patients will receive therapy using between 1-4 catheters depending on tumor dimensions and results from treatment simulation. Secondary endpoints for the part 2 study will include quality of life (QoL), safety, and median overall response rate.

In June 2021, the company announced that the data safety monitoring board (DSMB) had provided clearance to proceed to the 8th cohort of the study, with a 40% increase

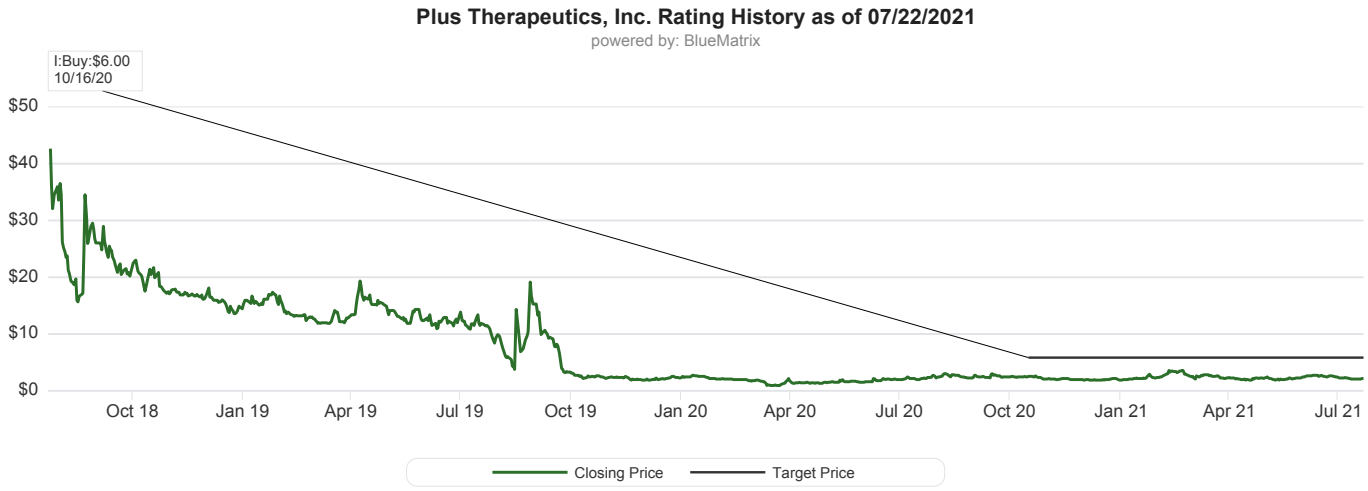
in total radioactivity. Patients in the 8th cohort are to be administered a 31.2mCi dose in 12.3mL, an increase from 22.3mCi and 8.8mL utilized in cohort seven.

Other indications currently being explored. The potential of the RNL platform is being explored in a range of PBCs. The company received positive feedback from the FDA, with Plus not requiring any additional toxicology or preclinical work. An IND is expected to be submitted, with the subsequent initiation of the Phase 1 ReSPECT-PBC trial in 2022. In a similar vein, the company also received positive feedback in 2Q21 regarding the RNL platform in leptomeningeal metastases (LM), which occurs when tumor cells metastasize to the membrane surrounding the brain and spinal cord. Management expects to submit an IND and initiate the Phase 1 ReSPECT-LM trial by YE21.

Plus Therapeutics: Income Statement ($000)																	
YE December 31	2019A	2020A	1Q21A	2Q21A	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Revenue:																	
Product																	
License																	
RNL - US	-	-	-	-	-	-	-	-	-	-	26,698	74,063	144,465	200,382	229,304	260,230	281,997
RNL- EU		-	-	-	-	-	-	-	-	-	28,840	80,006	156,058	216,462	247,704	281,113	304,627
Net revenue	-	-	-	-	-	-	-	-	-	-	55,538	154,070	300,522	416,845	477,008	541,343	586,624
Collaborative revenue:																	
Revenues																	
Other Income	6,998	303					-	-	-	-	-	-	-	-	-	-	-
		-					-	-	-	-	-	-	-	-	-	-	-
Total Collaborative Revenue	**6,998**	**303**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total Revenue	**6,998**	**303**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**55,538**	**154,070**	**300,522**	**416,845**	**477,008**	**541,343**	**586,624**
Gross Margins:																	
Cost of Goods Sold	-	-	-	-	-	-	-	-	-	-	27,769	61,628	90,157	104,211	119,252	108,269	117,325
Amortization of intangible assets	-																
%Gross Margin											50%	60%	70%	75%	75%	80%	80%
Gross Profit	6,998	303	-	-	-	-	-	-	-	-	27,769	92,442	210,366	312,634	357,756	433,075	469,299
Operating Expenses:																	
Research and Development	5,365	2,700	1,127	1,106	1,053	1,094	4,380	7,446	12,658	18,987	24,683	27,152	28,509	29,080	29,661	30,254	30,860
%R&D																	
In-process research and development acquired from NanoTx		781															
General and Administrative	5,290	6,406	1,352	1,469	1,999	2,076	6,896	8,965	11,654	19,812	29,718	44,577	53,493	64,192	70,611	74,141	75,624
%SG&A																	
Total Expenses	10,655	9,887	2,479	2,575	3,052	3,170	11,276	16,411	24,312	38,800	82,171	133,357	172,159	197,482	219,524	212,664	223,808
Operating Income (Loss)	(3,657)	(9,584)	(2,479)	(2,575)	(3,052)	(3,170)	(11,276)	(16,411)	(24,312)	(38,800)	(26,633)	20,712	128,363	219,362	257,484	328,679	362,816
	-	-					-	-	-	-	-	-	-	-	-	-	-
Interest income (expense)	(1,800)	(1,057)	(243)	(225)			(468)	-	-	-	-	-	-	-	-	-	-
Other income, net	-	-					-	-	-	-	-	-	-	-	-	-	-
Change in fair value of liability instruments	3,407	2,400	2				2	-	-	-	-	-	-	-	-	-	-
Issuance cost of warrants	(1,233)	-					-	-	-	-	-	-	-	-	-	-	-
		-					-	-	-	-	-	-	-	-	-	-	-
Total Other Income	**374**	**1,343**	**(241)**	**(225)**	**-**	**-**	**(466)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Pretax Income	(3,283)	(8,241)	(2,720)	(2,800)	(3,052)	(3,170)	(11,742)	(16,411)	(24,312)	(38,800)	(26,633)	20,712	128,363	219,362	257,484	328,679	362,816
Loss from discontinued operations	(7,604)																
Beneficial conversion feature for convertible preferred stock	(554)																
Taxes on income	-	-	-	-	-	-	-	-	-	-	-	-	-	4,387	12,874	16,434	29,025
Tax Rate														2%	5%	5%	8%
GAAP Net Income (Loss)	(11,441)	(8,241)	(2,720)	(2,800)	(3,052)	(3,170)	(11,742)	(16,411)	(24,312)	(38,800)	(26,633)	20,712	128,363	214,975	244,610	312,245	333,791
Foreign currency translation adjustments																	
Total comprehensive loss	(11,441)	(8,241)	(2,720)	(2,800)	(3,052)	(3,170)	(11,742)	(16,411)	(24,312)	(38,800)	(26,633)	20,712	128,363	214,975	244,610	312,245	333,791
GAAP-EPS	(8.27)	(1.86)	(0.33)	(0.25)	(0.27)	(0.28)	(1.11)	(1.07)	(1.32)	(1.90)	(1.15)	0.86	5.29	8.83	10.01	12.73	13.55
GAAP-EPS (Dil)	(8.27)	(1.86)	(0.33)	(0.25)	(0.27)	(0.28)	(1.11)	(1.07)	(1.32)	(1.90)	(1.15)	0.86	5.29	8.83	10.01	12.73	13.55
Wgtd Avg Shrs (Bas) - '000s	1,384	4,428	8,268	11,297	11,308	11,319	10,548	15,342	18,408	20,467	23,176	24,147	24,243	24,341	24,438	24,536	24,634
Wgtd Avg Shrs (Dil) - '000s	1,384	4,428	8,268	11,297	11,308	11,319	10,548	15,342	18,408	20,467	23,176	24,147	24,243	24,341	24,438	24,536	24,634

Source: Company reports and Maxim

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 07/22/21
		% 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%**	**53%**
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%**	**41%**
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.

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 received compensation for investment banking services from Plus Therapeutics, Inc. in the past 12 months.

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) index as the relevant index.

Valuation Methods

PSTV: We model commercialization of Rhenium Nanoliposome (RNL) in 2025 for recurrent glioblastoma. A 75% risk adjustment is factored in based on stage of development, clinical trial risk, and other factors. We do not factor in additional RNL programs or potential for pipeline assets. A 30% discount is applied to the free cash flow, 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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