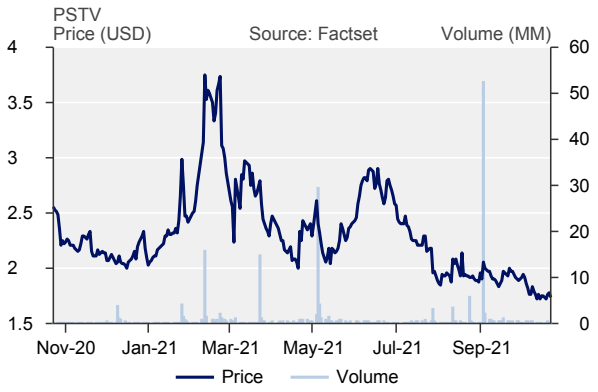
Biotechnology

PSTV - NASDAQ October 22, 2021

Closing Price 10/21/21	**$1.73**
Rating:	Buy
12-Month Target Price:	$6.00
52-Week Range:	$1.69 - $5.42
Market Cap (M):	26.5
Shares O/S (M):	15.3
Float:	98.1%
Avg. Daily Volume (000):	1,353.4
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	3,943
2Q	2,537	2,575A	4,114
3Q	1,396	3,499A	4,457
4Q	3,395	3,170	4,629
FY	9,887	11,705	17,144
Prior	—	11,276	16,411



EVENT INFORMATION

American Society for Radiation Oncology (ASTRO) Meeting

October 24-27, 2021

Society for Neuro-Oncology (SNO) Meeting

November 18-21, 2021

PSTV Abstract/Poster 11/19, 7:30–9:30pm

Plus Therapeutics-Hosted Roundtable on ReSPECT GBM Program

November 18, 2021, 4:00pm

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Plus Therapeutics, Inc.

Buy

Busy Autumn for Plus – ASTRO Meeting, SNO Meeting and a GBM Trial Roundtable, Also Expanding to Leptomeningeal Metastases

Summary

- **Plus reported 3Q21 results last night with a net loss of ($3.7M) and ended the period with $22.3M in cash on the balance sheet. The company should have sufficient runway at the current opex rate into late 2022. In addition, recall the P1/2 program for Rhenium Nanoliposome (RNL) in glioblastoma (GBM) has support from NIH/NCI.**
- **The P1 portion of the trial is enrolling the 8th cohort and 22 patients have been treated across all cohorts thus far. Importantly, with increasing volume, the higher 2.5 mCi/mL concentration and increased flow rate, the total absorbed radiation is increasing substantially and without dose-limiting toxicity. That's the point; hit the tumor with higher radiation with good volume and coverage, and do it safely. As such, the program is on track and the company is going to present at the upcoming Society for Neuro-Oncology (SNO) meeting in November. Other events are noted below.**
- **The company also announced on 10/19/21 an IND clearance for RNL in Leptomeningeal metastases (LM). A P1 trial is planned to start this quarter.**
- **Valuation. PSTV shares have pulled back since mid-June, mainly from a lack of near-term catalysts and more broad pullback in biotech valuations. That said, fundamentals remain intact, RNL continues to make progress, SNO meeting is next, P1 in LM too, and the company is sufficiently capitalized to reach its next data updates. Maintain Buy.**

Details

Rhenium Nanoliposome (RNL), initially developed for recurrent glioblastoma, is currently Plus's lead asset. RNL is a radioisotope-based therapy administered directly to the brain tumor via convection-enhanced delivery (CED), a technique that generates a pressure gradient at the tip of infusion catheters that are inserted through burr holes into interstitial spaces in the brain, driving flow. Using this technique, the therapeutic agent is able to bypass the blood-brain barrier. As the therapeutic agent is infused into the extracellular space, extracellular fluid is displaced. The liposomal encapsulation of Re-186 extends its intracranial half-life significantly and decreases the clearance rate from the brain; the drug is retained in the tumor area.

Manufacturing supply agreement. On 9/2/21, Plus announced that it has entered into an agreement with RadioMedix (private) for commercial production of Plus' radiopharmaceuticals. RadioMedix will manufacture GMP (good manufacturing practices) grade products, including Rhenium Nanoliposome (RNL, Re-186).

Glioblastoma program, Phase 1 (ReSPECT trial). This is a single arm, dose escalation study in patients with recurrent or progressive glioma that have already been treated with standard of care surgery/chemo/radiation. There are two parts to the study, with the first part evaluating safety and drug distribution, as well as determining the P2 dose. Part two 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 therapy and bevacizumab-naive.

The trial is enrolling up to n=55 patients, including the P1 portion of the study and the NIH/NCI is supporting the trial through P2. As of the last update in 3Q21, 22 patients had been enrolled and the program was dosing in the 8th cohort. The infused volume has risen from 0.66ml to 12.3ml and the total RNL activity in mCi (millicurie) has risen from 1.0, to 31.2 (cohort 8). Important to note is that starting at cohort 5, the concentration of RNL increased from 1.5 mCi/mL, to 2.5 mCi/mL. Cohort 6 and 7 also used the same volume and concentration but cohort 7 used a higher flow rate and achieved more than double the absorbed radiations. It's all about volume and

coverage to get the best results with RNL. No dose-limiting toxicities (DLTs) have been noted so far at absorbed radiation doses including a 40% increase in absorbed radiation in cohort 8 vs. cohort 7. Data will be taken to the FDA in 1H22 to discuss next steps.

Expansion to Leptomeningeal metastases (LM). On 10/19/21, Plus announced FDA clearance of the IND for RNL in treatment of LM. A P1 study is planned to start before YE21. The trial will be called ReSPECT-LM and will be a multi-center, sequential cohort, open-label, single dose, dose escalation study. The goal is to evaluate safety and dosing, with secondary measures around survival and duration of response.

Upcoming Events: The company will present interim data at both ASTRO (10/24 - 10/27) and SNO (11/18 - 11/21) as well as host a roundtable discussion on the GBM program on 11/18 (4:00pm ET).

Society for Neuro-Oncology Annual Meeting. SNO is taking place November 18-21, 2021, in Boston, Mass. Safety and feasibility data from the ongoing P1 ReSPECT trial will be presented as an abstract/poster on the 19th at 7:30pm ET.

Plus Therapeutics RNL poster:

Title	Safety and Feasibility of Rhenium-186 NanoLiposome (^{186}RNL) in Recurrent Glioma: the ReSPECT Phase 1 Trial
Date	November 19, 2021,at 7:30 – 9:30 p.m. ET
Location	Exhibit Hall D, Hynes Convention Center
Presenter	Andrew J. Brenner, M.D., Ph.D., Associate Professor of Medicine, Neurology, and Neurosurgery at The University of Texas Health Science Center at San Antonio and principal investigator of the ReSPECT clinical trial

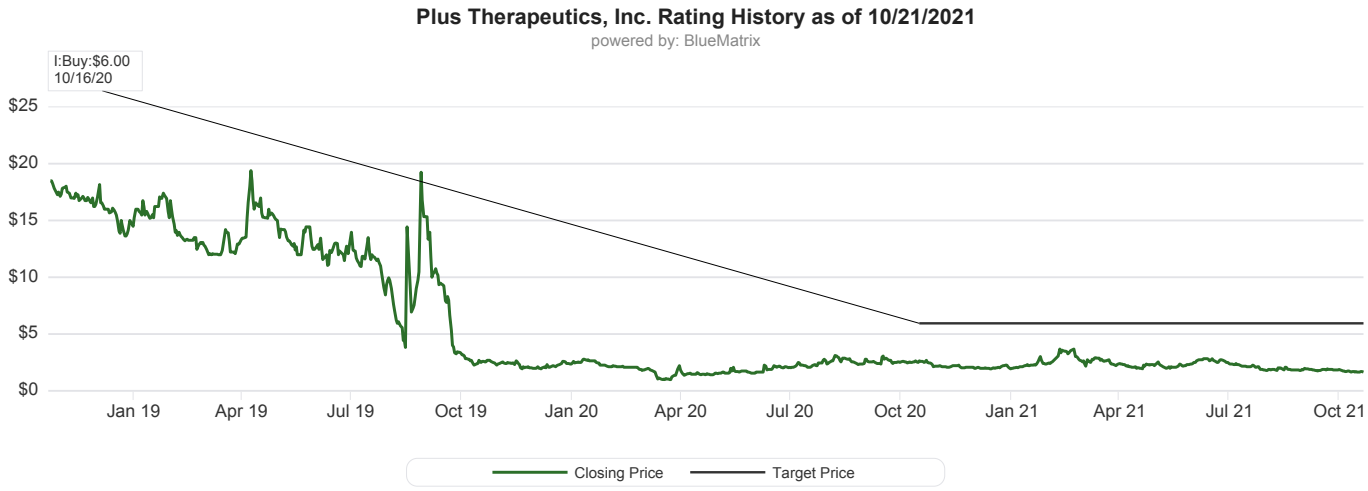
Management update: On 9/13/21, Plus announced the appointment of Norman Lafrance, M.D. as the company's Chief Medical Officer. His appointment begins on 12/8/21, and he joins Plus with 40 years of experience as a muclead medicine physician and as an executive in the pharma and healthcare industries.

Bio: Norman LaFrance, M.D. is the Chief Medical Officer and Senior Vice President at Plus Therapeutics. He was previously Chief Medical Officer and Senior Vice President at Jubilant Pharma Ltd., responsible for all Pharma Medical Regulatory Affairs activities. Prior to Jubilant Pharma, Ltd., Dr. LaFrance served as Global Chief Medical Officer at IBA Molecular from 2010 to 2012, and as Senior Vice President, Clinical Development and Chief Medical Officer at Molecular Insight Pharmaceuticals from 2007 to 2010. Prior to industry, Dr. LaFrance practiced medicine and held academic faculty appointments at Johns Hopkins University School of Medicine in the departments of medicine and radiology and the Department of Radiological Sciences in the Johns Hopkins School of Hygiene and Public Health. He is double board certified with fellowship status both in internal medicine and nuclear medicine, maintains active medical licensure in the U.S. along with active, professional society membership.

Plus Therapeutics: Income Statement ($000)																	
YE December 31	2019A	2020A	1Q21A	2Q21A	3Q21A	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	1,491	1,094	4,818	8,191	13,924	20,886	27,152	29,867	31,360	31,988	32,627	33,280	33,945
%R&D																	
In-process research and development acquired from NanoTx		781															
General and Administrative	5,290	6,406	1,352	1,469	1,990	2,076	6,887	8,953	11,639	19,786	29,680	44,519	53,423	64,108	70,519	74,044	75,525
%SG&A																	
Loss on disposal of property and equipment					18												
Total Expenses	10,655	9,887	2,479	2,575	3,499	3,170	11,705	17,144	25,563	40,672	84,600	136,014	174,940	200,307	222,398	215,593	226,796
Operating Income (Loss)	(3,657)	(9,584)	(2,479)	(2,575)	(3,499)	(3,170)	(11,705)	(17,144)	(25,563)	(40,672)	(29,062)	18,055	125,582	216,538	254,610	325,750	359,829
	-	-					-	-	-	-	-	-	-	-	-	-	-
Interest income (expense)	(1,800)	(1,057)	(243)	(225)	(227)		(695)	-	-	-	-	-	-	-	-	-	-
Other income, net	-	-					-	-	-	-	-	-	-	-	-	-	-
Change in fair value of liability instruments	3,407	2,400	2		2		4	-	-	-	-	-	-	-	-	-	-
Issuance cost of warrants	(1,233)	-					-	-	-	-	-	-	-	-	-	-	-
		-					-	-	-	-	-	-	-	-	-	-	-
Total Other Income	**374**	**1,343**	**(241)**	**(225)**	**(225)**	**-**	**(691)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Pretax Income	(3,283)	(8,241)	(2,720)	(2,800)	(3,724)	(3,170)	(12,396)	(17,144)	(25,563)	(40,672)	(29,062)	18,055	125,582	216,538	254,610	325,750	359,829
Loss from discontinued operations	(7,604)																
Beneficial conversion feature for convertible preferred stock	(554)																
Taxes on income	-	-	-	-	-	-	-	-	-	-	-	-	-	4,331	12,731	16,288	28,786
Tax Rate														2%	5%	5%	8%
GAAP Net Income (Loss)	(11,441)	(8,241)	(2,720)	(2,800)	(3,724)	(3,170)	(12,396)	(17,144)	(25,563)	(40,672)	(29,062)	18,055	125,582	212,207	241,880	309,463	331,042
Foreign currency translation adjustments																	
Total comprehensive loss	(11,441)	(8,241)	(2,720)	(2,800)	(3,724)	(3,170)	(12,396)	(17,144)	(25,563)	(40,672)	(29,062)	18,055	125,582	212,207	241,880	309,463	331,042
GAAP-EPS	(8.27)	(1.86)	(0.33)	(0.25)	(0.28)	(0.24)	(1.08)	(0.99)	(1.25)	(1.81)	(1.16)	0.69	4.79	8.05	9.14	11.65	12.41
GAAP-EPS (Dil)	(8.27)	(1.86)	(0.33)	(0.25)	(0.28)	(0.24)	(1.08)	(0.99)	(1.25)	(1.81)	(1.16)	0.69	4.79	8.05	9.14	11.65	12.41
Wgtd Avg Shrs (Bas) - '000s	1,384	4,428	8,268	11,297	13,264	13,277	11,527	17,303	20,377	22,441	25,159	26,137	26,242	26,347	26,453	26,559	26,665
Wgtd Avg Shrs (Dil) - '000s	1,384	4,428	8,268	11,297	13,264	13,277	11,527	17,303	20,377	22,441	25,159	26,137	26,242	26,347	26,453	26,559	26,665

Source: Company reports and Maxim

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 10/21/21
		% 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.	**88%**	**54%**
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.	**12%**	**44%**
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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