

In a Mixed Bag of MS Therapeutics' Innovation, a Few Stand Out; Reit. Buy on TGTX & TLSA; TGTX PT from \$23 to \$17

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Summary and Recommendation

We return to our sector thesis on Multiple Sclerosis (MS) therapeutics as this \$23B+ disease state category is in significant flux (Exhibit 1) with genericization within orals (methyl fumarate) and injectable drug class (interferon, natalizumab) anticipated to be counterbalanced by continued steep ramp of anti CD20 mAb drug class and steady build up of next-generation oral disease-modifying therapies serving as drivers of overall market growth to \$25B+ in 2028. While Relapsing MS (RMS) represents the largest patient segment (diagnosed prevalent cases of 750k+) and is the primary beneficiary of the transformative efficacy of anti CD20s, notably TGTX's (Buy; \$17 PT) ublituximab (ubli), secondary progressive (non-active form) and primary progressive MS makes up for the high unmet need disease states where we anticipate marginal impact of even the perceived "novel" drug classes, e.g., S1Ps, BTKis. To this end, we highlight the advent of novel neuroimmunology drug classes, particularly with disruptive mechanisms that have notable NT proof-of-concept catalysts, such as with Buy-rated TLSA's intranasal foralumab (anti CD3 fully human mAb) and ATRA's ATA188 (allogeneic T cell therapy targeting EBV). Amid a relatively scarce earlier-stage pipeline landscape, even for programs with primarily remyelination/neuroprotection focus, the low probability of success and expensive/long development cycles aren't particularly attractive in the present risk-off environment. Hence, the aforementioned market size/growth dynamics and relative dearth of scientific innovations (Exhibit 3) suggest to us a high likelihood of sector consolidation on the horizon in order to protect durability and/or profitability of certain MS franchises within large/mega-cap biopharmas, e.g., BIIB (Exhibit 2), BMY (via CELG), JNJ, NVS, Roche. Our TGTX PT decrease, from \$23 to \$17, takes into account aforementioned dynamics, including the recent delay to ongoing ubli BLA filing review, but largely ignores the substantially high premium commanded in case of an M&A scenario that could draw increased correlation to BIIB pursuing one of the few material strategic choices available to the neurology sector-leading large-cap biopharma.

Key Points

- **TLSA (Buy; \$3 PT): Second MS patient treatment data reaffirms safety and unprecedented efficacy of intra-nasal foralumab in non-active SPMS.** Having previously enrolled two patients, TLSA reported initial data on the first patient back in March, noting impressive whole-brain Foralumab treatment effects, including 3- and 6-month standardized uptake value ratio (SUVR) data, i.e., -23% and -38%, respectively, when compared to a pseudo reference region that showed minimal change in PET SUV across time points, implying an unprecedented effect on microglial activation not previously seen by even strong anti-inflammatory drugs such as Tysabri. ([link](#)) TLSA followed by reporting an updated look at the first patient, via their poster titled, "Nasal Anti-CD3 Monoclonal Antibody (Foralumab) Reduces PET Microglial Activation and Blood Inflammatory Biomarkers in a Patient with Non-Active Secondary Progressive MS" at the Consortium of Multiple Sclerosis Centers (CMSC) 2022 Annual Meeting, further highlighting data recently presented at 3/14 KOL event, including (1) stabilization of neurological measures, i.e., EDSS, pyramidal scale and timed 25-foot walk, (2) cytokine reductions of IL-6 (~25%), IFN-gamma (~13%), IL-18 (~2%), and IL-1beta (~63%), and (3) 35-50% reductions in positron emission tomography (PET) imaging following 6 months of Foralumab treatment, as well as noting a clean safety profile and favorable tolerability at 3- and 6-months for SPMS patient #1. Recently, on 6/8, TLSA reported positive clinical data on the patient #2 treated with intranasal Foralumab highlighted by a roughly 10-30% reduction in PET imaging signal, across all brain regions i.e., cortex, thalamus, white matter, and cerebellum, as well as clinical improvements in a neurological exam and in the timed 25-foot walk test, altogether consistent and validating data from the first patient treated. Notably, both patients are continuing their treatment, currently in their 13th and 4th month of treatment (#1 and #2, respectively). Recall, since Foralumab is a fully humanized anti-CD3 antibody that cannot crossreact with CD3 from other species and hence has had limitations to the scope of preclinical toxicology studies to evaluate longer-term exposure that allows for chronic dosing, the FDA required the first patient to demonstrate a clean safety profile following 3 months of treatment, then allowing treatment to continue to 6 months, at which point a second patient was also allowed to enroll. Now having received a "Study May Proceed" letter from the FDA permitting the ongoing Expanded Access IND program for intranasal Foralumab to enroll up to eight additional secondary progressive multiple sclerosis (SPMS) patients with collaborators at Brigham and Women's Hospital (BWH), we would expect for expedited enrollment, as well as potential for extended treatment periods.
- **TGTX (Buy; PT \$23 to \$17): 3-month ublituximab PDUFA delay to Dec. 28th isn't unprecedented and passes our smell test on clinical and CMC modules to not mean materially higher regulatory risk.** (*continued on pg. 2*)

Analyst certification and important disclosures can be found on pages 11 - 15 of this report.

This document represents an abbreviated discussion of the subject issuer and should not be used as the sole basis for an investment decision. Contact your B. Riley Securities representative for complete research concerning the subject issuers, including research briefs and reports.

Partly impacted by FDA staffing issues, we acknowledge general challenges with the current regulatory environment especially for perceived relatively less urgent, me-too innovations by FDA such as TGTX's ublituximab. This is somewhat further exacerbated by (1) ubli being part of the combination regimen, U2, albeit at much higher doses, that showed an imbalance in survival outcome in Ph. III CLL (leukemia) study; and (2) ULTIMATE-1 & 2 MS studies recruiting <10% subjects from U.S. and 80%+ from Eastern Europe, notably 45-55% from Russia/Ukraine with randomization balance information not fully disclosed as TGTX is yet to release publication manuscript. That said, we don't believe the delay in any way implies an elevated regulatory risk for approval as the FDA information request pertains to reorganization of the summary of existing datasets submitted as part of the original BLA. Since the original Ph. III ULTIMATE-1 & 2 topline data disclosure, TGTX has had several abstracts/presentations from the pivotal program be presented at numerous major neurology medical conferences. TGTX only recently learned that the company's response to FDA was deemed as a major amendment and thus issued a PR on 5/31. Interestingly, the two prior anti CD20 approvals, Roche's Ocrevus and NVS' Kesimpta, also experienced 3-month delay as part of their FDA review. NVS released a high-level PR indicating that "regulatory action had been delayed from June to September 2020 and based on a company submission in response to routine review questions, Novartis will continue to work with the FDA to complete the review as soon as possible;" while the Ocrevus delay was attributed to "a result of the submission of additional data by Roche regarding the commercial manufacturing process for Ocrevus." On the latter, TGTX has had longstanding relationship with global biologics' CDMO leader, Samsung Biologics, with specific sites manufacturing ubli likely already complying with FDA's standards. We view the delay to have minimal impact on TGTX's launch preparedness activities as the company had always planned for a late-4Q22/1Q23 launch. Longer term, we remain bullish on the potential for ubli to compete as a fast-follower with best-in-class annualized relapse rate, acceptable safety profile, and a streamlined one-hour dosing regimen which will be particularly appealing to high-volume infusion centers that have noted capacity constraints to have somewhat impacted new patient starts and hence revenues throughout FY21. Roche's Ocrevus and NVS' Kesimpta are already responsible for 50% of total new scripts, outperforming original estimates of 40% in 2021; and we currently forecast a modest penetration rate of 6% for ubli in 2025, two years post launch and \$450M in risk-adjusted sales based on a 70% probability of success and believe ubli can ramp up to capture 20% of the anti-CD20 market by 2030, yielding \$1.7B in revenues to TGTX. On the heels of the PDUFA delay and exit from oncology markets, we are lowering our 12-month price target from \$23 to \$17, reflecting an increased cost of capital consistent with the macro environment; and moderate adjustments to SG&A and R&D expenditures over time as TGTX continues to invest in building a strong brand to compete with large pharma anti-CD20 players NVS and Roche. We believe the company will start to generate meaningful revenues in the 2H23 timeframe with the potential for upside, particularly on market penetration rates as the anti-CD20 class continues to grow as a whole within the RMS therapeutics landscape, and physicians, payers, and patients grow more comfortable with the overall safety and efficacy profile and more convenient dosing regimen upon a potential approval before YE22.

- **Exploratory analyses from the Consortium of Multiple Sclerosis Centers (CMSC) annual meeting and upcoming AAN presentations provide incremental validation for ubli's potent effect on both clinical and functional outcomes.** TGTX recently presented, (1) an oral presentation, "*Reduced Disease Progression With Ublituximab vs Teriflunomide in the Phase 3 ULTIMATE I and II Studies in Relapsing Multiple Sclerosis*"; and (2) two posters showcasing the cognitive benefit experienced by ubli treated patients and additional analyses of infusion related reactions observed in the ULTIMATE I&II studies. In our view, the incremental data presented nicely support a robust body of evidence provided to the FDA and bode favorably for a future commercial launch of ubli and contributes to physician's, payer's, and the Street's growing appreciation for the breadth of ubli's therapeutic potential. Dr. Enrique Alvarez highlighted ubli as the most potent anti-CD20 with respect to antibody-dependent cellular cytotoxicity (ADCC) activity with robust and durable B cell depletion to nearly undetectable levels maintained through an average of 55 weeks from the last dose. The presentation also provided an overview of the impact of ubli on disability, including (1) 5.9% of patients with confirmed disability progression (CDP) relative to 5.2% on teriflunomide at 12-weeks and 4.8% of patients relative to 3.3% on teriflunomide at 24-weeks; (2) mean EDSS scores of 2.8/2.5 at baseline relative to 4.2/3.3 at week 96 for teriflunomide/ubli patients; and (3) 85.3%/76.3% of patients free of disability progression at week 96. The company also presented a poster underscoring the cognitive benefit associated with ubli treatment, disclosing an improvement in processing speed using the Symbol Digit Modalities Test (SDMT), i.e., ubli was associated with a mean 4.1 increase in SDMT score from baseline at

Week 96 and mean change from baseline in SDMT score was 2.8 vs 1.2, 3.8 vs 2.7, and 5.0 vs 2.5 for ubli vs

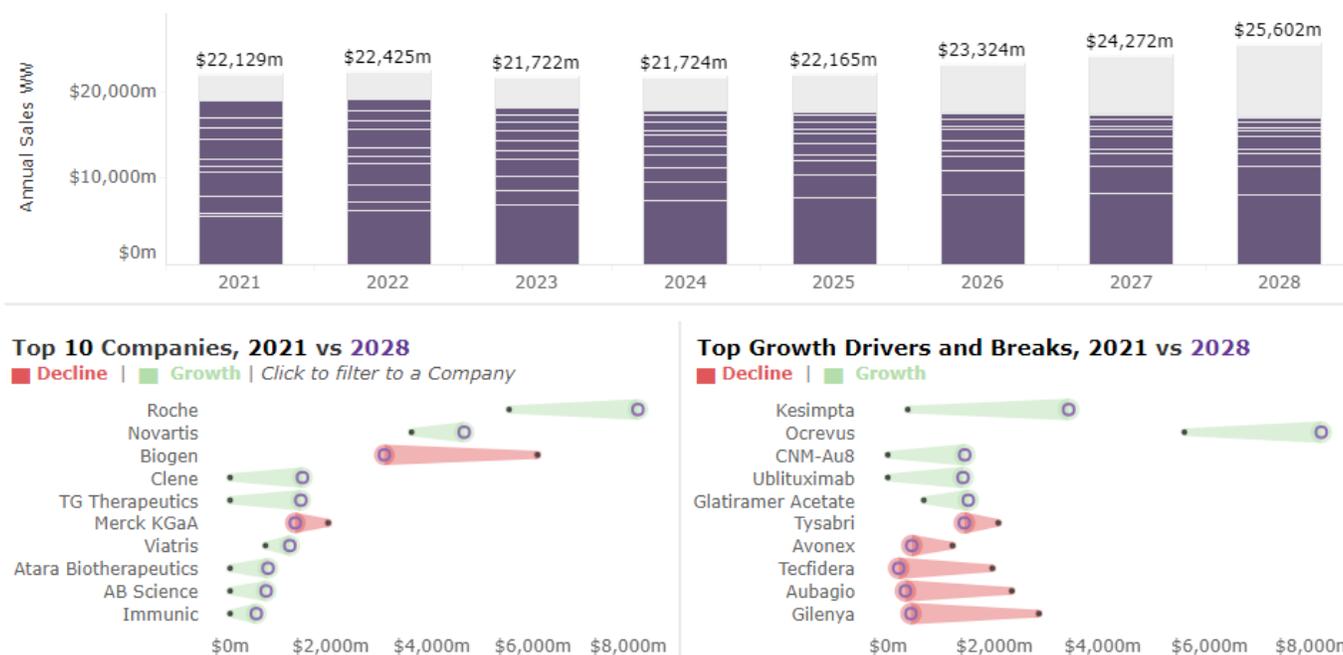
teriflunomide at Weeks 24, 48, and 96, respectively. We also reiterate the competitive advantage of ubli's streamlined 1-hour dosing regimen; and TGTX reported that 96.6% of participants completed infusions without interruption with 94.6% of patients going through maintenance doses 2-5 within 1 hour. Additionally, 43% of ubli-treated patients had an infusion related reaction at Dose 1, which decreased to <10% for all subsequent infusions and 69.5% did not have any IRR recurrences. Whereas Ocrevus administration requires intravenous pre-treatment, thereby increasing overall chair time in infusion centers, the administration route of premedications via the oral, IV, or IM route did not impact the frequency of IRRs.

- **MNOV (Buy; \$6 PT): Ph. III ready, MNOV, looks to continue steady, capital-efficient, progression with substantially de-risked profile in non-active SPMS.** Recall, MNOV has previously reported positive Ph. IIb data, meeting their primary endpoint and demonstrating a 48% reduction in the rate of progression of whole brain atrophy, as well as an overall favorable safety and tolerability profile. Following MN-166 treatment patients demonstrated a reduced risk of progression of 26%, i.e., 19% MN-166 patients showed disability progression vs 24% of placebo treated patients. Importantly, these data reflect both patients with PPMS and SPMS. When broken down and compared to marketed drug, OCREVUS, MN-166 treatment demonstrated a 29% reduction in disability progression in PPMS patients compared to OCREVUS' 24%. Moreover, MN-166 also demonstrated a risk reduction of 46% in SPMS patients without relapse, a key demographic since currently approved drugs have been limited to relapse in SPMS patients. Of note, when compared to OCREVUS' 17.5% or MAYZENT's 15% reduction in brain atrophy, MN-166's 48% reduction in brain atrophy bodes well for MN-166. When risk reduction is taken together with safety profiles, including label warnings consisting of serious infusion reactions, infections and cancer for OCREVUS, and warnings for infections, macular edema, brady-arrhythmia, respiratory effect, liver injury, increased blood pressure and fetal risk for MAYZENT, MN-166's benign safety demonstrating no significant issues, with gastrointestinal side effects being the most common adverse reaction, begin to set it apart, in our view. Now ready to begin a Ph. III trial in progressive MS, MNOV continues to execute wisely, currently in ongoing discussions with potential partners, MNOV will enroll subjects with SPMS without relapse, the subgroup which previously demonstrated the highest efficacy in the Ph. IIb trial, with an FDA aligned primary endpoint of 3-month confirmed disability progression, as measured by EDSS.
- **Looking beyond our MS universe, highlight progress of two uncovered programs.**
 - **Within the progressive MS landscape, ATRA's ATA188 also plans to present an interim analysis** from the Ph. II EMBOLD study within 2Q22, evaluating ATA188 in patients with progressive MS, representing a TAM of 1.2M patients WW. Recall, ATA188 was granted fast track designation as an allogeneic T cell therapy targeting Epstein-Barr virus (EBV) thought to be an underlying cause of MS. Previously published data in *Nature* ([link](#)) has suggested a mechanistic link for the association between MS and EBV as it relates to the high-affinity molecular mimicry between the EBV transcription factor EBV nuclear antigen 1 (EBNA1) and the central nervous system protein glial cell adhesion molecule (GlialCAM) with prior EBV infection necessary for a patient to develop MS. ATRA has demonstrated a favorable safety and tolerability profile for ATA188 with some patients receiving up to 3 annual treatments and up to 42 months of follow up and 6/7 patients achieving confirmed EDSS improvement (CDI) with longest follow up 39+ months and ongoing. Sustained EDSS improvement is supportive of the potential to arrest and/or reverse disease progression and ATRA will interrogate EDSS improvement at 6 months and biomarker analyses in the upcoming EMBOLD interim analysis in order to inform a future Ph. III trial design as well as the expansion into additional therapeutic areas.
 - **Recent Ph. II ulcerative colitis setback has no readthrough for IMUX's IMU-838 pivotal program in MS.** IMUX's drug candidate, vidofludimus calcium, or IMU-838, is a DHODH inhibitor currently in Ph. III trial for relapsing-remitting MS. Built on Ph. II EMPHASIS trial results, which showed 62% and 70% reduction of combined unique active (CUA) MRI lesions at doses of 45 mg/day and 30 mg/day, respectively, the Ph. III ENSURE 1&2 trials (NCT05134441&NCT05201638) will enroll ~1,050 patients each to receive 30 mg/day IMU-838 or placebo, with interim analysis planned after approx. half of the events occurred.

Despite the negative [readout](#) of IMU-838 in Ph. II CALDOSE-1 trial for ulcerative colitis (UC), we continue

the see the potential of IMU-838 in MS, as the monotherapy effect of IMU-838 was observed in UC patients. The underperforming clinical efficacy in UC patients with concurrent use of corticosteroids was likely due to potential drug-drug interaction between IMU-838 and steroids, which, in our view, has no impact on the MS treatment outcomes being evaluated in ongoing Ph. III pivotal program.

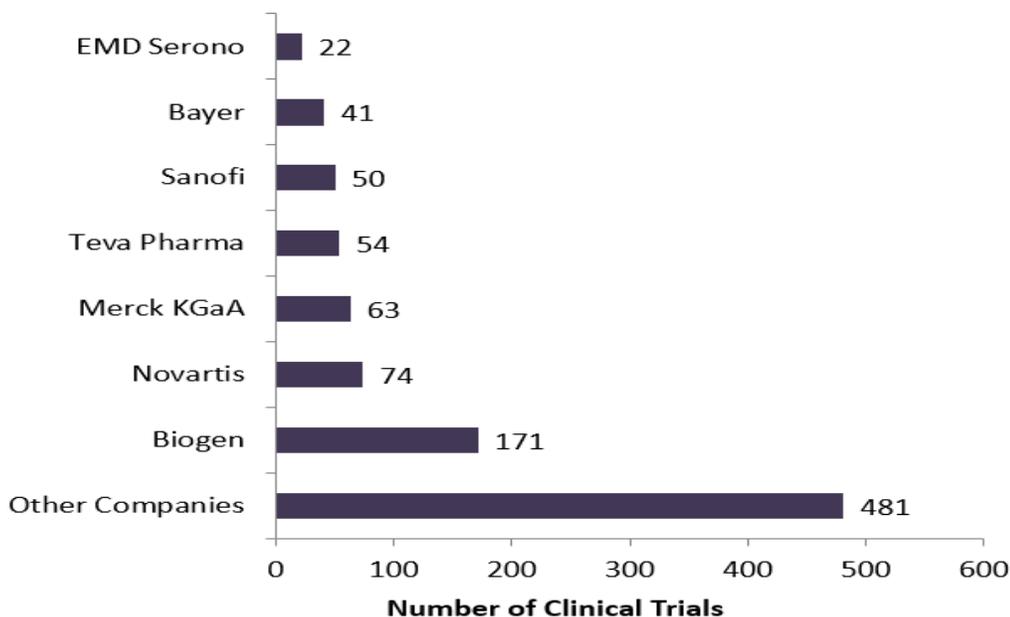
Exhibit 1: MS Therapeutics’ Market in Significant Flux, While Still Maintaining >2% CAGR (2021-28)



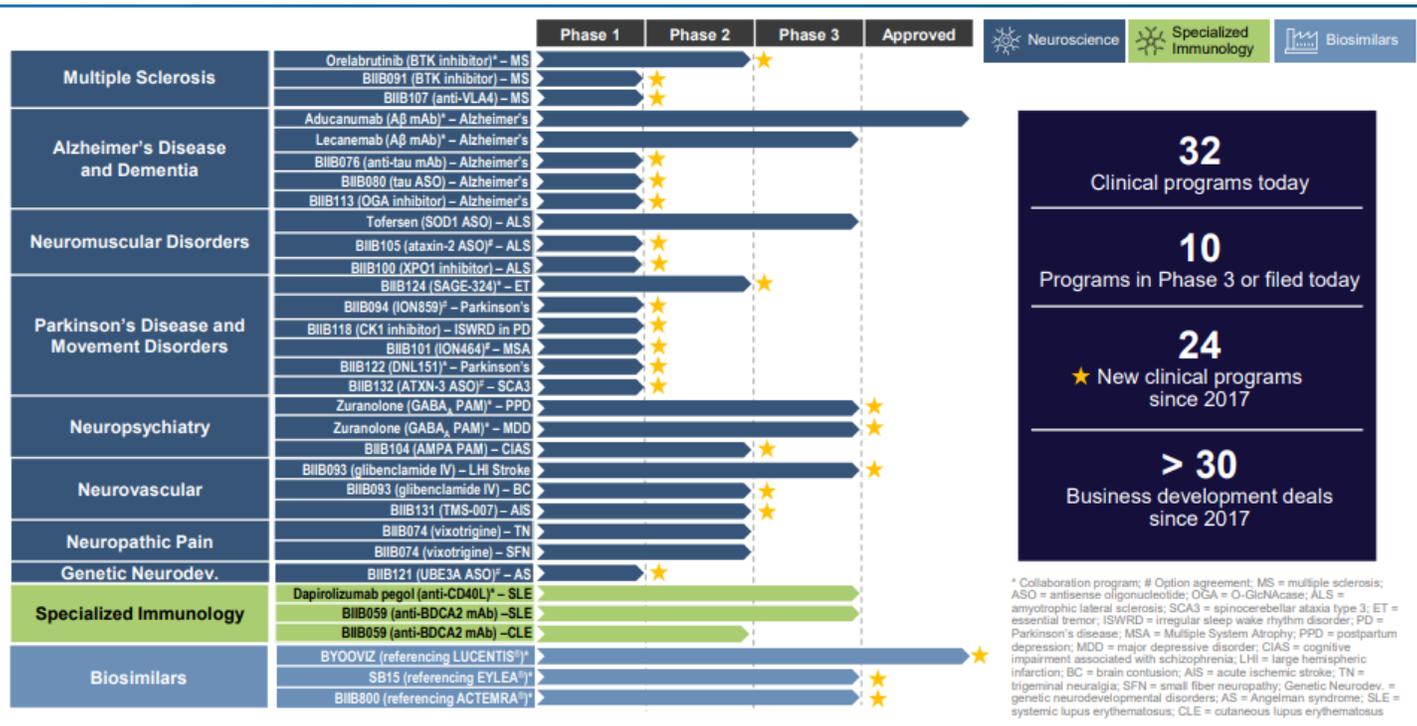
Source: Evaluate Pharma

Exhibit 2: BIIB’s Relatively Challenged Positioning Within the MS Therapeutics’ Innovation Ecosystem

Top Industry Sponsors of MS Clinical Trials

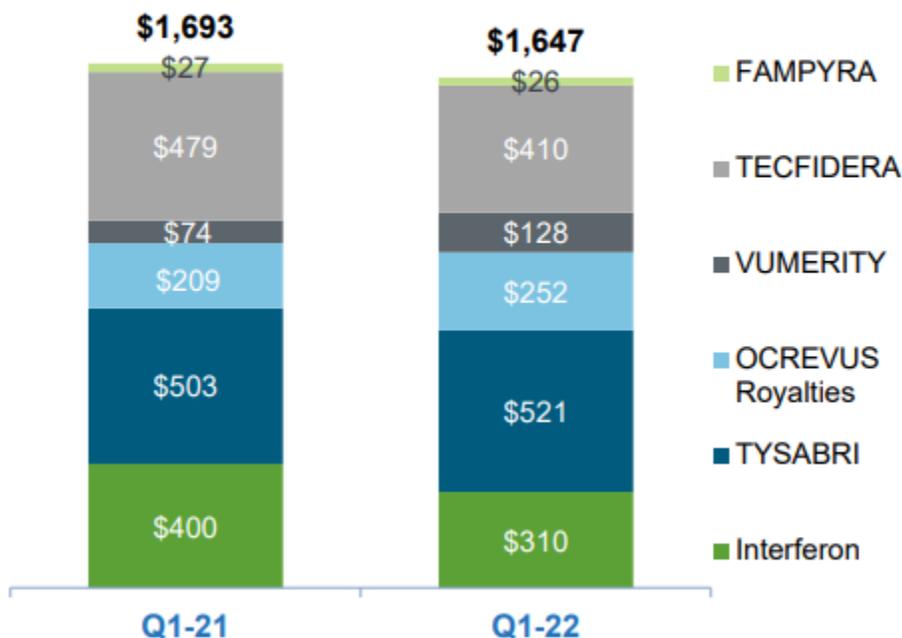


Source: GlobalData



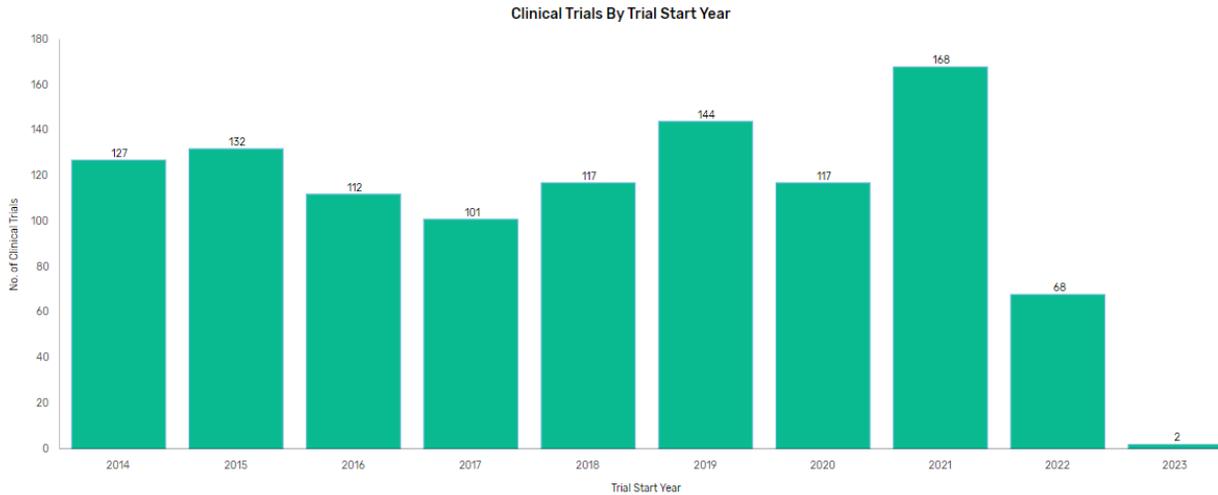
Source: BIIB Company Filings

MS Revenue (\$M)

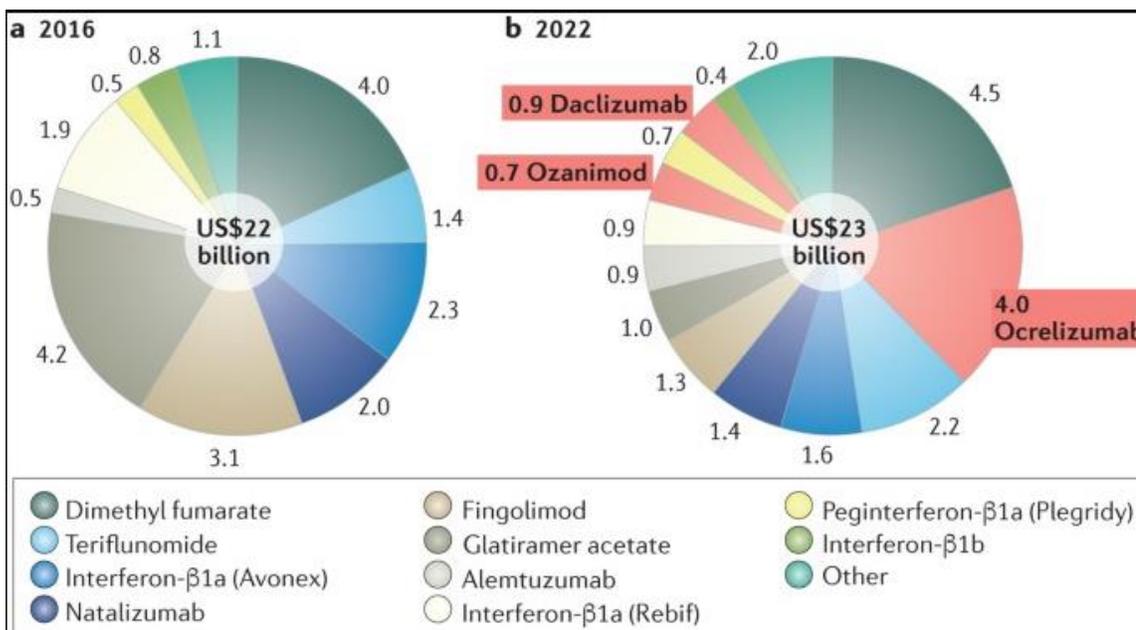


Source: BIIB Company Filings

Exhibit 3: Despite Continued R&D Investments, the MS Landscape Remains Largely Dominated by the Anti-CD20 Class



Class	Drug	U.S. Approval Date	Route of Administration	Dosing	Global 2018 Revenues by Drug/Class (\$ in millions)
Interferons	BETASERON (interferon beta-1a)	1993	Subcutaneously	1x / 2 days	\$643
	AVONEX (interferon beta-1a)	1996	Intramuscularly	1x / week	\$1,915
	Rebif®	2002	Subcutaneously	3x / week	\$1,732
	EXTAVIA (interferon beta-1a)	2009	Subcutaneously	1x / 2 days	\$162
	plegridy (peginterferon beta-1a)	2014	Subcutaneously	1x / 2 weeks	\$448
IV Potent Immunomodulators	TYSABRI (natalizumab)	2004	Intravenously	1x / 4 weeks	\$1,864
	LEMTRADA (climuzumab)	2014	Intravenously	3x / year	\$475
T-Cell Targeted Orals	GILENYA (siponimod)	2010	Orally	1x / day	\$3,380
	AUBAGIO (teriflunomide)	2012	Orally	1x / day	\$1,945
	Tecfidera (dimethyl fumarate)	2013	Orally	2x / day	\$4,274
CD20s	OCREVUS (ocrelizumab)	2017	Intravenously	2x / year	\$2,406 * Now >\$4B+
	Ofatumumab	2020	Subcutaneously	1x / 4 weeks	TBD
	Ublituximab	2021	Intravenously	2x / year	TBD



Source: BrileyFin, TGI Company Filings, Westad et al. "The Multiple Sclerosis Market." Nature Reviews Drug Discovery Accessed June 2022. 11100 Santa Monica Blvd., Ste. 800 Los Angeles, CA 90025 | www.brileyfin.com

TG Therapeutics (TGTX)
Income Statement

\$ in millions, except EPS	2017A	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21A	2021A	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E
Revenue	0.2	0.2	0.2	0.2	0.8	1.5	2.0	2.3	6.7	3.2	0.0	0.0	0.0	3.2	109.8	261.5	457.4
Product revenue	0.0	0.0	0.0	0.0	0.8	1.5	2.0	2.3	6.5	3.2	0.0	0.0	0.0	3.2	109.8	261.5	457.4
Collaboration and license revenue	0.2	0.2	0.2	0.2	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cost of sales	0.0	0.0	0.0	0.0	0.1	0.1	0.3	0.2	0.8	0.3	0.0	0.0	0.0	0.3	17.6	41.8	54.9
Gross profit	0.2	0.2	0.2	0.2	0.7	1.4	1.7	2.1	5.9	2.9	0.0	0.0	0.0	2.9	92.2	219.6	402.5
Research and development	(102.5)	(159.4)	(154.2)	(165.9)	(63.1)	(44.9)	(52.0)	(62.6)	(222.6)	(40.5)	(25.5)	(15.5)	(16.0)	(97.5)	(117.0)	(128.7)	(132.5)
Sales, general and administrative	(16.3)	(15.2)	(15.0)	(107.9)	(26.8)	(34.0)	(34.9)	(32.4)	(128.1)	(30.8)	(33.3)	(39.9)	(43.1)	(147.0)	(164.1)	(188.4)	(219.7)
Operating income (loss)	(118.7)	(174.4)	(169.1)	(273.6)	(89.2)	(77.5)	(85.1)	(92.9)	(344.770)	(68.4)	(58.8)	(55.4)	(59.1)	(241.6)	(188.8)	(197.4)	(50.3)
Interest income (expenses)	0.3	0.9	(5.3)	(6.3)	(1.9)	(1.6)	(1.0)	(1.1)	(5.6)	(1.7)	(1.7)	(1.7)	(1.7)	(6.8)	(7.6)	(7.2)	(8.1)
Other income (loss)	(0.1)	0.1	1.5	0.5	0.5	0.6	0.5	0.7	2.3	0.6	0.6	0.6	0.6	2.4	2.5	2.7	2.8
Net income before income taxes	(118.5)	(173.5)	(172.9)	(279.4)	(90.6)	(78.5)	(85.6)	(93.3)	(348.1)	(69.5)	(59.8)	(56.5)	(60.1)	(246.0)	(193.9)	(101.9)	45.0
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.5
Net income from continuing operations	(118.5)	(173.5)	(172.9)	(279.4)	(90.6)	(78.5)	(85.6)	(93.3)	(348.1)	(69.5)	(59.8)	(56.5)	(60.1)	(246.0)	(193.9)	(101.9)	40.5
Net income (loss) to common stockholders	(118.5)	(173.5)	(172.9)	(279.4)	(90.6)	(78.5)	(85.6)	(93.3)	(348.1)	(69.5)	(59.8)	(56.5)	(60.1)	(246.0)	(193.9)	(101.9)	40.5
Basic EPS attributable to common stockholders	(1.9)	(2.3)	(2.0)	(2.42)	(0.69)	(0.59)	(0.65)	(0.70)	(2.63)	(0.48)	(0.41)	(0.38)	(0.38)	(1.65)	(1.16)	(0.59)	0.23
Diluted EPS attributable to common stockholders	(1.9)	(2.3)	(2.0)	(2.42)	(0.69)	(0.59)	(0.65)	(0.70)	(2.63)	(0.48)	(0.41)	(0.38)	(0.38)	(1.65)	(1.16)	(0.59)	0.23
Shares, basic (million)	62.1	75.5	88.4	115.3	131.9	132.1	132.4	132.6	132.2	143.3	146.2	149.1	156.6	148.8	167.0	172.8	173.2
Shares, diluted (million)	62.1	75.5	88.4	115.3	131.9	132.1	132.4	132.6	132.2	143.3	146.2	149.1	156.6	148.8	167.0	172.8	173.2

Cash Flow Statement

\$ in millions	2017A	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21A	2021A	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E
Fully diluted shares outstanding	44755.7	(14.1)	70.7	440.8	(81.9)	(69.8)	(74.9)	(27.8)	(254.5)	(58.6)	(15.8)	(19.8)	104.3	10.1	111.7	102.1	91.2
Cash and cash equivalents at beginning of period	25.6	0.1	(14.0)	113.9	497.5	415.6	345.8	270.8	554.7	243.0	184.4	168.6	148.8	300.2	310.2	421.9	524.0
Cash and cash equivalents at end of period	0.1	(14.0)	56.7	554.7	415.6	345.8	270.8	243.0	300.2	184.4	168.6	148.8	253.1	310.2	421.9	524.0	615.2
CASH FLOWS FROM OPERATING ACTIVITIES																	
Consolidated net loss	(118.5)	(173.5)	(172.9)	(279.4)	(90.6)	(78.5)	(85.6)	(93.3)	(348.1)	(69.5)	(59.8)	(56.5)	(60.1)	(246.0)	(193.9)	(101.9)	40.5
Adjustments to reconcile consolidated net loss to net cash used in operating activities:	44724.0																
Non-cash stock compensation expense	15.9	12.9	11.3	80.3	16.6	16.3	14.0	14.4	61.3	16.6	16.3	14.0	17.4	64.3	67.6	70.9	74.5
Shares issued in connection with in-licensing agreement	0.0	4.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Depreciation and amortization	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.3	0.0	0.0	0.0	0.0	0.1	3.6	8.1	13.3
Amortization of premium on investment securities	0.1	(0.1)	(0.3)	(0.0)	0.1	0.2	0.1	0.1	0.5	0.1	0.1	0.1	0.2	0.5	0.6	0.6	0.7
Amortization of debt issuance costs	0.0	0.0	0.8	0.9	0.2	0.2	0.2	0.4	1.1	0.3	0.3	0.3	0.3	1.1	1.2	1.3	1.4
Amortization of leasehold interest	0.1	0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.3
Non-cash change in lease liability and right-of-use asset	0.0	0.0	2.5	2.3	0.5	0.5	0.5	0.5	1.9	0.5	0.5	0.5	0.6	2.0	2.1	2.3	2.4
Change in fair value of notes payable and accrued interest	0.1	(0.1)	0.1	0.7	(0.1)	(0.2)	(0.1)	(0.3)	(0.6)	(0.2)	(0.1)	(0.1)	(0.2)	(0.6)	(0.6)	(0.7)	(0.7)
Changes in assets and liabilities:																	
Increase in other current assets	(2.7)	(1.6)	1.4	2.3	(4.1)	(0.3)	(2.8)	(1.3)	(8.5)	(2.3)	(2.1)	(2.1)	(2.8)	(9.4)	(10.3)	(11.3)	(12.5)
Increase in accounts receivable	0.0	0.0	0.0	0.0	(0.8)	(0.2)	(0.5)	(0.0)	(1.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Increase (decrease) in accrued interest receivable	(0.0)	0.0	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Decrease in other assets	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Increase (decrease) in accounts payable and accrued expenses	11.0	11.0	(4.8)	11.6	0.9	2.4	8.8	3.9	16.0	4.4	4.0	4.0	5.2	17.6	19.3	21.3	23.4
Decrease in lease liabilities	0.0	0.0	(1.5)	(2.0)	(0.5)	(0.5)	(0.5)	(0.5)	(2.0)	(0.6)	(0.5)	(0.5)	(0.7)	(2.2)	(2.4)	(2.7)	(2.9)
Increase in interest payable	0.0	0.0	1.5	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Increase in other liabilities	0.0	18.4	28.8	(31.5)	(3.7)	(0.1)	(1.4)	(10.9)	(16.1)	(4.4)	(4.0)	(4.0)	(5.2)	(17.8)	(19.5)	(21.5)	(23.6)
Increase in deferred rent	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Decrease in deferred revenue	(0.2)	(0.2)	(0.2)	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	(0.0)	(0.0)	(0.0)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)
Net cash provided by/(used in) operating activities	44630.2	(128.9)	(132.8)	(214.5)	(81.4)	(60.2)	(67.2)	(86.9)	(295.6)	(55.0)	(45.4)	(44.4)	(45.3)	(190.1)	(132.3)	(33.6)	116.3
CASH FLOWS FROM INVESTING ACTIVITIES																	
Proceeds from maturity of short-term securities	19.8	32.5	29.3	43.3	17.0	11.8	11.3	15.6	55.6	0.0	30.0	25.0	0.0	55.0	0.0	0.0	0.0
Investment in held-to-maturity securities	(28.0)	(31.2)	(29.8)	(67.4)	(17.4)	(14.1)	(11.8)	(12.2)	(55.5)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Purchases of equipment	(0.0)	(0.1)	(0.1)	(0.4)	(0.1)	(0.2)	(0.1)	(0.1)	(0.4)	(3.6)	(0.4)	(0.4)	(0.4)	(4.8)	(6.0)	(14.4)	(25.2)
Net cash provided by/(used in) investing activities	(8.2)	1.2	(0.7)	(24.5)	(0.5)	(2.5)	(0.6)	3.3	(0.3)	(3.6)	29.6	24.6	(0.4)	50.2	(6.0)	(14.4)	(25.2)
CASH FLOWS FROM FINANCING ACTIVITIES																	
Payment of loan payable	0.0	0.0	0.0	0.0	0.0	(7.2)	(7.2)	(15.6)	(30.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from sale of common stock, net	131.5	113.6	175.0	679.7	0.0	0.0	0.0	2.2	2.2	0.0	0.0	0.0	150.0	150.0	250.0	150.0	0.0
Proceeds from debt financing	0.0	0.0	30.0	0.0	0.0	0.0	0.0	70.0	70.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from the exercise of warrants and options	2.1	0.0	0.0	0.1	0.1	0.0	0.1	(0.0)	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financing costs paid	0.0	0.0	(0.8)	0.0	(0.2)	0.0	0.0	(0.8)	(1.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by/(used in) financing activities	133.7	113.6	204.2	679.8	(0.1)	(7.2)	(7.1)	55.8	41.4	0.0	0.0	0.0	150.0	150.0	250.0	150.0	0.0

TG Therapeutics (TGTX)
DCF analysis

Fiscal year	2018A	2019A	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	Terminal value
Fiscal year end date	12/31/18	12/31/19	12/31/20	12/31/21	12/31/22	2020A	12/31/24	12/31/25	12/31/26	12/31/27	12/31/28	12/31/29	12/31/30	
Revenues	0.2	0.2	0.2	6.7	3.2	109.8	261.5	457.4	700.0	952.4	1,214.8	1,487.4	1,686.4	
Cost of product sales	-	-	-	0.8	0.3	17.6	41.8	54.9	84.0	114.3	145.8	178.5	202.4	
Gross Profit	0.2	0.2	0.2	5.9	2.9	92.2	219.6	402.5	616.0	838.1	1,069.0	1,308.9	1,484.0	
R&D expense	(159.4)	(154.2)	(165.9)	(222.6)	(97.5)	(117.0)	(128.7)	(132.5)	(136.5)	(140.6)	(144.8)	(149.1)	(153.6)	
SG&A expense	(15.2)	(15.0)	(107.9)	(128.1)	(147.0)	(164.1)	(188.4)	(219.7)	(258.5)	(298.9)	(338.3)	(379.2)	(409.0)	
Total operating expenses	(174.6)	(169.2)	(273.7)	(350.7)	(244.5)	(281.1)	(317.0)	(352.2)	(395.0)	(439.5)	(483.1)	(528.3)	(562.6)	
Operating income (EBIT)	(174.4)	(169.1)	(273.6)	(344.8)	(241.6)	(188.8)	(97.4)	50.3	221.0	398.6	585.9	780.6	921.4	
Taxes	-	-	-	-	-	-	-	4.5	32.4	59.0	122.0	162.7	192.4	
After tax operating income	(174.4)	(169.1)	(273.6)	(344.8)	(241.6)	(188.8)	(97.4)	45.8	188.6	339.6	463.9	617.9	729.0	
(+) depreciation and amortization	0.1	0.1	0.2	0.3	0.1	3.6	8.1	13.3	18.9	23.8	27.9	31.2	32.0	
(-) capital expenditures	(0.1)	(0.1)	(0.4)	(0.4)	(4.8)	(6.0)	(14.4)	(25.2)	(38.5)	(52.4)	(66.8)	(81.8)	(92.8)	
(-) change in working capital	(30.9)	(22.4)	24.3	(7.6)	(6.8)	(7.5)	(8.2)	(9.1)	(10.0)	(11.0)	(12.1)	(13.3)	(14.6)	
(+) deferred taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(+) other non-cash items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Unlevered free cash flow	(205.3)	(191.5)	(249.5)	(352.5)	(253.1)	(198.7)	(111.9)	24.8	159.0	300.1	413.0	554.0	653.7	
Time period (years)			-	-	0.85	1.85	2.85	3.85	4.85	5.85	6.85	7.85	8.85	
Discount factor				1.0	0.9	0.8	0.7	0.6	0.6	0.5	0.4	0.4	0.3	
PV					(228.15)	(158.51)	(78.99)	15.49	87.89	146.81	178.79	212.27	221.62	
EV	2,230.6													PV of Terminal Value
+ Cash and Cash equivalents	280.7													2,054.99
Company value	2,511.3													
- Long-term debt	76.6													
Equity value	\$2,435													
Fully diluted shares outstanding	142.8													
Price/share	\$ 17.00													
WACC	13.0%													
Terminal growth rate	2%													
Assumptions		WACC Calculations				Balance Sheet								
Date	6/12/2022	Risk-free rate	2.0%		Total debt	76.64								
Fiscal year ending (1-12)	12	Adjusted beta	1.2		Cash and equivalents	280.70								
Fiscal year ending (month)	December	Rm-Rf	7.4%		Net debt	(204.07)								
Projections discounted to (1-12)	12.00	Re	11.0%		Debt, as a % of equity	11.69%								
Projections discounted to (month)	December	Rd	0.0%		Cash per share	\$ 1.97								
Shares outstanding	142.817	WACC, calculated	11.0%		Closing price, 06-12-22	\$ 4.59								
					MC (\$M), 06-12-22	\$ 655.5								

Valuation

MediciNova, Inc. (MNOV)

We derive our 12-month \$6 price target on a discounted cash flow (DCF) analysis of revenue and cash flow projected through 2030. We use a 14.5% discount rate, in line with other early clinical-stage biotech companies, and a 2% terminal growth rate.

TG Therapeutics, Inc. (TGTX)

Our TGTX \$17 PT uses a DCF with a WACC of 13.0% and a perpetuity growth rate of 2.0%, with (1) relapsing multiple sclerosis programs at \$15.03; and (2) cash of \$1.97.

Tiziana Life Sciences Plc (TLSA)

We base our Buy rating and 12-month price target of \$3 per share on a discounted cash flow (DCF) analysis of revenue and cash flow projection through 2030. Our projections of free cash flow to the firm from sales of oral foralumab for moderate to severe Crohn's disease and nasal foralumab for non-active SPMS are adjusted and weighted based on historical regulatory approval rates of similar treatments at similar stages of development. Our DCF analysis applies a WACC-calculated 14.5% discount rate and a 2% terminal growth rate, in line with other clinical-stage biotech companies, yielding an implied enterprise value of \$78M. For 2030, the final projected year of our model, we forecast \$500M in total risk-adjusted revenue, which assumes a 35% probability of clinical and regulatory success for oral foralumab and 25% for nasal foralumab. Of note, nasal foralumab could potentially pursue approval via orphan drug designation, in our opinion, intended for rare diseases or conditions that affect less than 200,000 individuals in the U.S. Through this regulatory pathway, TLISA will be able to have the agency involved in the early stages regarding the trial design and endpoint selection and likely facilitate expedited approval, given the unmet need. We currently do not ascribe any value in our model to TZLS-501 and miliclib, as we await additional clinical data and subsequent guidance on the regulatory path to market.

Risks

MediciNova, Inc. (MNOV)

Clinical risk. It is uncertain if clinical efficacy and safety for MN-166 and MN-001 will be observed in current and future clinical trials, particularly the newly initiating Ph. III PMS and ALS trials.

Regulatory risk. The regulatory pathway for MNOV's pipeline candidates could be uncertain, and it is unclear whether positive data will be sufficient for regulatory filing. Additionally, there is no certainty that MN-166 and MN-001 will be approved and/or reimbursed. If the regulatory path is more complex and/or time consuming than anticipated, there could be a materially negative impact on our estimates and price target, even with success in achieving clinical endpoints.

Commercialization risk. The market potential of MediciNova's therapies may not be as significant as projected. In particular, we highlight competition for MN-166 in the Progressive Multiple Sclerosis therapeutics space from Ocrevus from Roche and siponimod from Novartis. In addition, MediciNova will need to establish a sales and medical affairs infrastructure in the U.S., Europe, and other geographies for its pipeline candidates.

Financing risk. With approximately \$75M in cash, MediciNova will likely need to raise additional capital for continued clinical candidate development, perhaps via additional equity or convertible debt financing, before reaching profitability, likely resulting in equity share dilution. MediciNova is likely to be seeking partners for ibudilast in progressive MS and ALS, and the company is likely to seek an up-front payment to limit dilution to shareholders from future equity raises.

Stock price volatility. Share price volatility is common for developmental biopharma firms like MediciNova.

TG Therapeutics, Inc. (TGTX)

Clinical risks. At this time it is uncertain if the safety and efficacy data reported from the ublituximab program will be sufficient to support regulatory approval in MS. Negative safety and/or efficacy findings in either program could expose our price target to downward revisions.

Regulatory risks. At this time it is unclear whether the positive data generated will be sufficient for a Biologic Licensing Application (BLA) approval in the U.S. for ublituximab in MS. Additionally, there is no certainty that any of TGTX's drugs will be approved or reimbursed. If the regulatory path for TGTX's candidates is more complex and/or time-consuming than anticipated, there could be a materially negative impact to our estimates and price target, even with success in achieving clinical endpoints.

Commercialization risks. The market potential of TGTX's therapies may not be as significant as projected. For relapsing MS, we highlight competition from Ocrevus from Roche and Kesimpta from Novartis and Genmab. In addition, TGTX will need to establish a sales and medical affairs infrastructure in the U.S., Europe, and other geographies for various pipeline candidates.

Financing risk. With approximately \$280M in pro-forma cash as of Mar 2022, TGTX may need to raise additional capital for continued clinical and preclinical candidate development.

Stock price volatility. Share price volatility is common for developmental biopharma firms like TGTX.

Tiziana Life Sciences Plc (TLSA)

Clinical risks. It is uncertain whether the clinical benefit observed in the clinical studies for foralumab and future registrational trials will be sufficient to support regulatory approval in the U.S., Europe, and other countries. Negative safety and/or efficacy findings in these trials could lead to downward revisions to our price target.

Regulatory risks. The regulatory pathway for all of TLSA's programs in the U.S. is uncertain, and it is unclear whether positive data will be sufficient for a New Drug Application (NDA) submission for each program in the U.S. Additionally, there is no certainty that any of TLSA's drugs will be approved or reimbursed. If the regulatory path for TLSA's candidates is more complex and/or time-consuming than anticipated, there could be a materially negative impact to our estimates and price target, even with success in achieving clinical endpoints.

IP risks. The patent protection related to foralumab and other candidates may expire in the near term and be subject to litigations from competitors. For example, the methods of use patent, pertaining to autoimmune or Inflammatory disease and disorder, for foralumab is expected to expire in 2025.

Commercialization risks. The market potential of TLSA's therapies may not be as significant as projected. In addition, TLSA will need to establish a sales and medical affairs infrastructure in the U.S., Europe, and other geographies for foralumab and other pipeline candidates.

Financing risk. With approximately \$66M in cash and cash equivalents, TLSA will likely need to raise additional capital for continued clinical and preclinical candidate development, perhaps via additional equity financing, before reaching profitability, likely resulting in equity share dilution.

Stock price volatility. Share price volatility is common for developmental biopharma firms like Tiziana Life Sciences.

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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