August 10, 2020

Biotechnology

Companies mentioned:

ANVS	**Buy**
Target Price:	$12.00
Closing Price:	$5.55
Market Cap (M):	38.1
Avg. Daily Volume:	852.1
BCLI	**Buy**
Target Price:	$20.00
Closing Price:	$12.79
Market Cap (M):	403.2
Avg. Daily Volume:	742.0
INMB	**Buy**
Target Price:	$16.00
Closing Price:	$10.66
Market Cap (M):	143.4
Avg. Daily Volume:	1,017.3
SAVA	**Hold**
Target Price:	NA
Closing Price:	$2.95
Market Cap (M):	73.1
Avg. Daily Volume:	4,232.9

Biotechnology

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Is Amyloid Back? Aducanumab Gets Priority Review, but What Seems to be Back in Favor is the Alzheimer's Space

Summary

- **Shares of Biogen (BIIB - NR) rose 10% on Friday in response to announcing that the FDA has accepted for review the BLA for aducanumab and not only that, but the drug will also have priority review. The PDUFA is set for March 7, 2021.**
- **Will aducanumab gain an approval? Recall the phase 3 data in March 2019 was questionable at best, in our view; while there were positive signals in efficacy, dosing schedule and safety concerns were raised. This for many, including us, signaled the likely end of the amyloid hypothesis. However, our view was that the larger positive from the aducanumab outcome was that it reinvigorated the Alzheimer's disease (AD) space around other therapeutics targets like inflammation.**
- **Whichever side of the aducanumab debate one lands, one thing seems to be irrefutable—that so much has been learned through all these amyloid trials, and now there is opportunity for other approaches, which we viewed as overshadowed by amyloid for decades. This is not the first time in scientific and medical history that this has happened; it happened with antibiotics and T cells, among other 'mega-discoveries', several of which we discuss briefly below.**
- **So is amyloid over? Maybe, maybe not; the aducanumab BLA is being reviewed. An interesting take on its potential could be perhaps the drug gets the narrowest of labels. Sure, Biogen is hoping for much more but consider what that could do for the AD space as a whole? A new drug finally gets to AD patients. We'll see what happens, but in our view, AD is back in favor.**
- **We highlight the following companies in our universe that have been active in the AD space: Annovis Bio (ANVS - Buy), Brainstorm Cell Therapeutics (BCLI - Buy) Cassava Sciences (SAVA - Hold), INmune Bio (INMB - Buy).**

Details

Can adacanumab gain an approval? Biogen (BIIB - NR) announced on Friday that the FDA has accepted the BLA for aducanumab, the company's monoclonal antibody candidate for Alzheimer's disease (AD). The FDA has granted aducanumab priority review, with a PDUFA date of March 7, 2021, which is a significant positive. The FDA may act upon Biogen's BLA earlier under an expedited review. The FDA plans on holding an Advisory Committee meeting; the date has yet to be determined but the outcome will likely impact BIIB shares as well as other AD-focused names in the space, in our view.

The BLA submission included data from the company's Phase 3 EMERGE and ENGAGE studies, as well as its Phase 1b PRIME study. The EMERGE study (N=1,638) met its primary endpoint, achieving a significant 23% reduction in clinical decline in Clinical Dementia Rating-Sum of Boxes (CDR–SB) scores at 78 weeks compared to placebo (p=0.01). While the ENGAGE study (N=1,647) failed to meet its primary endpoint, a subset of the data may complement and support the results seen in the EMERGE study. ENGAGE and EMERGE were both parallel-group studies. The program in AD was essentially considered a fail by many, including us. However, the positive takeaway was that it seemed to spur renewed interest in the AD space targeting therapeutic approaches away from amyloid beta, the amyloid hypothesis. While Biogen surprised the world with its plans to still file a BLA, we believe the entire AD space benefited from opportunities for other therapeutic approaches to be highlighted, particularly those involving inflammation pathways.

Beyond amyloid beta, Biogen set the stage for other players in the AD space to capture some focus. The space in general... *(continued on pages 2+)*

has pivoted away from the amyloid theory, in light of multiple clinical trial failures including aducanumab in March 2019, and is looking at other novel approaches to AD. Could the new BLA submission be indicative of a rekindled interest in the amyloid theory? We will have to wait and see. Other pathways, such as those targeting inflammation, particularly in more upstream areas of signaling pathways (casting wider nets) are being evaluated as potential drivers of AD.

The risk in one-sided science/medicine can come with a high price. Non-amyloid approaches and a renewed interest in AD. Is it actually new? No, not at all. In fact, leaders in the space pointed to TNF as a culprit in AD (meaning inflammation), back in the early 1990s. As it happens in science and medicine, a tectonic-like discovery can shift the entire space in one direction or another, overshadowing other approaches. This is the what happened with amyloid beta, which essentially drowned out everything else in AD. Other examples include the discovery of penicillin in the 1920s by Alexander Fleming, which overshadowed sulfonamides and convalescent serum (sound familiar? The latter has re-emerged with COVID therapeutics). B cells and humoral immunity, the antibody side of the immune system was all but forgotten in the 1980s when T cells were thought to be basically all that mattered. A lot of this stemmed from AIDS and HIV discovery work, which was done with all the right intentions, but inadvertently quelled the advancement of other approaches. There are other examples. However, in our view, the risk of one theory or discovery suppressing the progress of another is the lack of debate and controversy. One of the most powerful forces that drives innovation is debate and controversy, especially in science and medicine with two or more different approaches or theories going back and forth with data, publication and discussion. If there is one and only one, like amyloid beta, how can there ever be any progress? Especially if that one sided-theory is wrong? If B cells were not overrun by T cells work, maybe drugs like Keytruda and other checkpoints could've been discovered, put through trials, and saved lives decades earlier--something to think about.

The point is that large, space-shifting discoveries overshadow other approaches, for better or worse in some cases. However, at the end of the day, science and medicine will emerge and have its proverbial day in the sun because there are academic, private, and public companies, etc. that continue to innovate even when something like amyloid beta is dominating attention and dollars. From an AD perspective, it was no accident that the Enbrel anti-inflammatory impact on AD story surfaced in May 2019 (in the newspapers too, LINK), or rather resurfaced. That study/observation was several years old, but buried in the literature as amyloid beta was at its peak with groups like Lilly (LLY - NR) driving solenezumab through phase 3 trials. Then it was aducanumab and Biogen's turn, and here we are today. Will the BLA have success? We'll see, but let's look at several companies in our research universe that have had early success targeting non-amyloid pathways.

Annovis Bio (ANVS - Buy) recently announced it had received institutional review board approval to initiate its Phase 2 study of ANVS401, its oral small molecule compound, in N=68 Alzheimer's disease (AD) and Parkinson's disease (PD) patients. The study will evaluate the progression of nerve cell death in both indications by assessing steps in the toxic cascade that ultimately culminate in cell death. ANVS2401 interferes with translation of three neurotoxic proteins implicated in AD and PD, as well as other CNS-related neurodegenerative diseases, amyloid precursor protein/Aß (APP), tau/phospho-tau (tau), and α–synuclein (#SYN). Reducing the neurotoxic levels could potentially halt the cascade of toxic proteins and stop or slow disease progression. This mechanism of action was confirmed in three previous P1 studies (125 healthy subjects, combined), whereby a reduction was observed in the cerebrospinal fluid levels of the toxic proteins, as well as in inflammatory markers in patients with mild cognitive impairment. ANVS401 is currently being evaluated in another Phase 2a double-blind, placebo-controlled study in patients with AD, in collaboration with the Alzheimer's Disease Cooperative Study (ADCS). Data for the Phase 2a studies in AD alone and AD+PD are expected in late 2020 and 2021, respectively.

BrainStorm Cell Therapeutics (BCLI - Buy) is planning an open-label, 40 patient, phase 2 study in AD. The mechanism of action of NurOwn cells, which are autologous cells derived from a patient's bone marrow and cultured (not genetically modified, which cannot be overstated, in our view) to super-secrete neuronal growth factors, lends itself as a potential therapeutic for multiple

neurodegenerative diseases. For AD, the 52-week trial will enroll 40 patients with prodromal to mild AD. Patients will be administered three intrathecal injections of NurOwn eight weeks apart. The trial will be conducted at various sites in Europe. As opposed to other therapies, the NurOwn platform may target multiple disease pathways, which could increase the likelihood of a positive outcome for patients. NurOwn may possess synergistic qualities with other anti-beta amyloid or anti-tau therapies. Note, the company is also conducting a Phase 2 program in progressive multiple sclerosis (MS) and a Phase 3 in amyotrophic lateral sclerosis (ALS). The latter is due to report top-line data (fully enrolled) before YE-20. What links these diseases together is the inflammation component and dying neurons. As such, cell therapy like NurOwn was extended from ALS first to MS and now to AD. More indications could follow.

INmune Bio (INMB - Buy) is developing a PEGylated protein that selectively neutralizes human soluble TNF (sTNF) called XPro1595. Human sTNF is an inflammatory cytokine that is elevated in the cerebrospinal fluid and brain (post-mortem) of patients with certain neurodegenerative disorders such as Alzheimer's, as well as in advanced cancers. XPro1595 is a dominant negative TNF inhibitor that forms heterotrimers with native sTNF (but not membrane-bound TNF), thereby sequestering sTNF away from TNF receptors. By disrupting the biological activity of sTNF and preventing receptor interaction, XPro1595 selectively decreases the activation of TNFR1, as sTNF has greater affinity to TNFR1 relative to TNFR2, which allows for more precise targeting. XPro1595 can effectively and selectively neutralize >99% of sTNF within minutes when its concentration is at least 10-fold higher than the native sTNF concentration. Further, by sparing transmembrane TNF (tmTNF), XPro1595 maintains the protective roles of TNF, which occur primarily through TNFR2 signaling, differentiating it from the FDA-approved first-generation anti-TNF biologics (approved for the treatment of autoimmune disorders such as rheumatoid arthritis) that inhibit both sTNF and tmTNF. Of note, XPro1595 does not cause immunosuppression and demyelination, which are the primary complications of currently available nonselective TNF inhibitors, as it does not interfere with the role of tmTNF in immunity.

XPro1595 is currently undergoing a phase 1b study evaluating its efficacy in treating patients with AD. This open-label, multi-center study (N=18) in Australia was initiated to evaluate weekly subcutaneous administration of XPro1595 (DN-TNF) in 3 cohorts (at 3 doses: 0.3mg/kg, 1.0mg/kg, 3.0mg/kg) of mild-to-moderate AD patients for 3 months. To date, two cohorts (0.3mg/kg and 1.0mg/kg) have been enrolled and evaluated. The primary endpoints include safety as well as evaluation of chosen biomarkers, including a novel imaging biomarker to measure free water (FW) content in white matter. By measuring FW (or edema) in the white matter of the whole brain by MRI, which is representative of neuroinflammation in the brain, patients with AD can be differentiated even from those with mild cognitive impairment as well as from 'normal' patients. In an interim data readout, a reduction in neuroinflammation in AD patients (n=6) administered XPro1595 was noted compared to noncurrent AD patients (n=25) from the database of the Alzheimer's Disease Neuroimaging Initiative (ADNI).

Specifically, while whole brain inflammation increased by 5.1% in ADNI patients, at the higher dose of 1mg/kg, XPro1595 inflammation decreased by 2.3%. Notably, in the arcuate fasciculus (a major white matter bundle), which plays a key role in speech processing, a 40.6% (ranging from 20%-70%) reduction in neuroinflammation was seen in all patients treated (n=6), whereas the ADNI cohort had a 4.6% increase in neuroinflammation in this region. Taken together, while small in number, the data suggest that the drug is active in this critical domain of cognition. INmune continues to enroll and has introduced an extension arm to evaluate the drug beyond the initial 12-week follow up, given both KOL and study-patient enthusiasm for the drug. We think KOL interest should help expedite enrollment, which has also been hampered (like most clinical trials) by the COVID-19 environment. Combined, there may be between >24 total patient data by YE20.

Cassava Sciences (SAVA - Hold) is targeting inflammation via restoration of aberrant protein filamin A with its oral small-molecule drug candidate PTI-125. FLNA is a scaffolding protein that may be altered in conformation by Aß42. The alterations then allow Aß42-induced toxic signaling cascades that ultimately lead to neuroinflammation and neuronal damage via several mechanisms including over-production of inflammatory cytokines, tau hyperphosphorylation,

neurofibrillary tangles (NFTs), Aß plaque formation, loss of synapses, and other changes. The aberrant signaling is through the alpha-7 nicotinic acetylcholine receptor (alpha-7nAChR) and TLR4. The latter induces cytokine release, an inflammatory response. PTI-125 may correct the altered FLNA and restore 'normal' signaling.

While Cassava missed in its P2b trial, the company did report substantial variability among biomarkers in its control group. The company is re-assessing lymphocyte and plasma samples from all trial participants, which could provide additional information on target engagement, and re-assess cerebrospinal fluid (CSF) biomarkers, in addition to the potential impact of PTI-125 on cognition; topline data readout is expected in 2H20. In the Phase 2b study, N=64 patients were randomized into one of three groups receiving BID dosing of either placebo, 50mg, or 100mg of PTI-125 for 28 days. The primary endpoint was significant improvement in AD biomarkers from baseline to day 28 in treatment cohorts vs. placebo. While the trial was a miss, post-hoc analysis highlighted substantial variability in AD biomarker levels in the placebo cohort, with CSF levels of CSF-tau and p-tau varying from -54% to +34%, and -49% to+253%, respectively, from baseline to day 28.

DISCLOSURES

Annovis Bio, Inc. Rating History as of 08/07/2020

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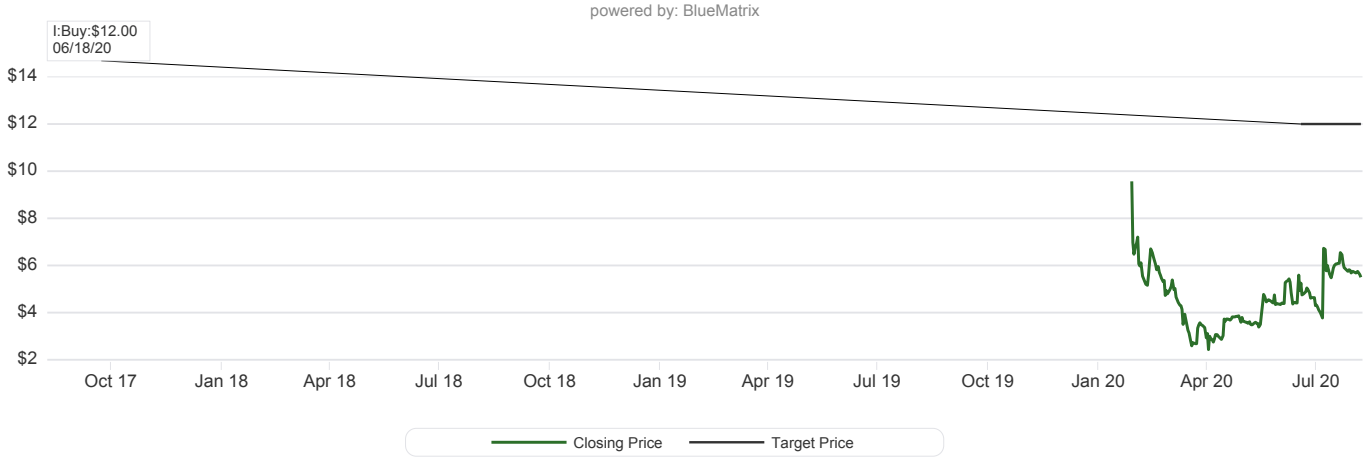

Cassava Sciences, Inc. Rating History as of 08/07/2020

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BrainStorm Cell Therapeutics Inc. Rating History as of 08/07/2020

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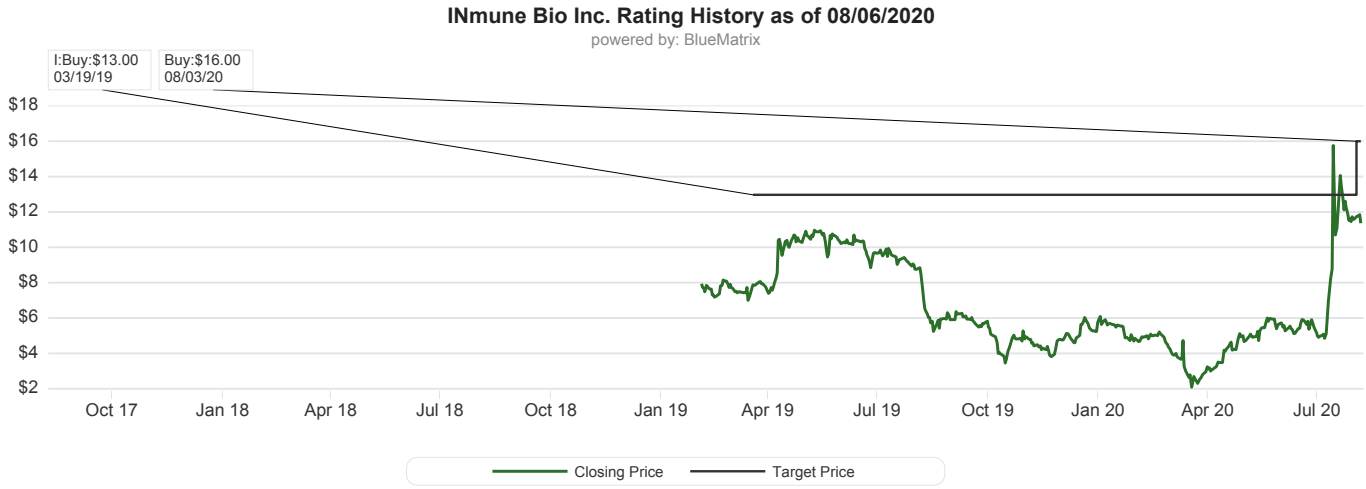

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		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**80%**	**50%**
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.	**20%**	**39%**
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*		

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ANVS: For Annovis Bio, we use the BTK (ARCA Biotechnology Index) as the relative index.
SAVA: For Cassava Sciences, we use the BTK (NYSE Arca Biotechnology Index) as the relevant index.

BCLI: For BrainStorm Cell Therapeutics, we use the BTK (NYSE Biotechnology Index) as the relevant index.
INMB: For INmune Bio, we use the BTK (NYSE Arca Biotechnology Index) as the relevant index.

Valuation Methods

ANVS: We model commercialization of ANVS401 in the US for AD-DS and PD in 2025, followed by AD in 2027. A risk adjustment of 80% is applied to our therapeutic models based on stage of development, clinical trial risk, and other factors. 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.
SAVA: Typically, we apply a 30% discount to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target. However, we do not factor in PTI-125 and the company does not have a pipeline asset to value as of now. As such, we do not publish a price target at this juncture.
BCLI: We model commercialization of NurOwn in ALS in 2021, MS in 2024, and AD in 2025. Risk adjustments of 50% (ALS) and 90% (MS and AD) are applied to our therapeutic models based on stage of development, clinical trial risk, and other factors. A discount rate of 30% is then used in our FCFF, EPS, and SOP models to derive a price target.
INMB: We model INBO3 for solid tumors, in 2026 (US) and 2027 (EU, AUS), INKmune for r/r ovarian cancer in 2026 (US) and 2027 (EU), and XPro1595 in Alzheimer's disease in 2025 (US) and 2026 (EU, AUS). Risk adjustments are factored in based on stage of development, clinical trial risk and other factors; 50% IO, 70% AD. A 30% discount is applied to the FCF, dEPS, and SOP Models, which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks

ANVS: Aside from general market and other economic risks, risks particular to our price target and rating for Annovis Bio 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; (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. (10) The company is heavily dependent on the potential of ANVS401, which contains the active pharmaceutical ingredient in ANVS405 (injectable) as well. Failure of ANVS401 to have clinical success could impact the company's ability to operate. (11) Delays related to COVID-19 could impact the company's ability operate and impact also clinical trials. (12) The company is targeting two indications in Alzheimer's disease and Parkinson' disease which are spaces dominated by larger companies and organizations which have signifcantly more resources.
SAVA: Aside from general market and other economic risks, risks particular to our price target and rating for Cassava Sciences include: (1) the regulatory and clinical risk associated with product development; (2) the ability to access capital and the very high likelihood that the company will need to raise additional capital; (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 reliance on collaborators and/or potential collaborators from which there could be unforeseen delays and expenses; (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; (10) inability, if product(s) is/are approved to gain adequate market share and maintain adequate revenue growth; (11) the ability of the company to maintain its exchange listing; (12) the company had setbacks in its analgesic programs around Remoxy and is attempting to transition to a new focus in Alzheimer's disease and may not be successful; (13) the company has a limited operating history in Alzheimer's disease; (14) following the P2b fail for PTI-125, the path forward for Cassava is subject to significant uncertainty as the company's ability to continue to operate.
BCLI: Aside from general market and other economic risks, risks particular to our price target and rating for BrainStorm Cell Therapeutics include the following: (1) the clinical efficacy of the product; (2) the management of the clinical trial process; (3) the manufacturing of the product; (4) the competitive landscape for this product; (5) the decisions of regulatory bodies, such as the European Union and FDA; (6) the reimbursement environment. Small-capitalized biotechnology companies possess unique risks and shares can be very volatile. Our ability to 'predict' data based on small and limited patient numbers in early (phase I or II) trials is limited. As such, investors should expect these risks, which are typically commensurate with the reward potential. Additional risks 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; (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) capital raised via equity financing or convertible debt securities will have a dilutive effect for investors; (14) delays related to COVID-19 could impact the company's ability operate and impact also clinical trials; (15) foreign currency exchange rate fluctuations.
INMB: Aside from general market and other economic risks, risks particular to our price target and rating for INmune Bio include: (1) the regulatory and clinical risk associated with product development; (2) the ability to access capital and the very high likelihood that the company will need to raise additional capital; (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 reliance on collaborators and/or potential collaborators from which there could be unforeseen delays and expenses; (6) the requirements for marketing authorization from regulatory bodies in the United States and other countries, as well as potential differences in clinical trial requirements in different regions; (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; (10) inability, if product(s) is/are

approved to gain adequate market share and maintain adequate revenue growth; (11) competion in the immune oncology and neurodegenerative disease spaces from companies and groups with more advanced programs and greater resources.

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

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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.

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