2016 Biotech Preview: TSRO Our Top Pick; Pricing, Immuno-Onc Trends to Continue

Summary

Our top biotech pick for 2016 is TSRO. We like VARUBI's chances of success and think two data readouts in 1H16 for the PARP inhibitor niraparib could be even larger catalysts for the stock. Also, TSRO's checkpoint inhibitors should begin to command attention as they enter the clinic. For the industry, we expect drug pricing commentary to continue to be a headwind, large pharma to continue to use small cap bio to plug pipeline holes, and see no let-up in the focus on immuno-oncology.

Key Points

- **Our top pick for 2016 is TSRO.** We are positive on the launch of VARUBI given management's track record in the CINV setting, and we think two data readouts for niraparib in 2Q16 could be even more significant catalysts. TSRO's early-stage checkpoint inhibitors are entering the clinic as well, which could command additional focus from investors.

- **Only 11 months till the election.** We expect drug pricing to continue to be in the cross-hairs of stump speeches and candidate tweets, though it could always be supplanted by numerous other topics- whatever makes poll numbers go up. Should the pricing issue remain a headline, we could see more stories of alternative pricing models being developed, such as "pay-for-performance".

- **We expect big pharma to continue to look to smaller biotech companies to bolster growth and plug holes in pipelines.** Development collaborations are likely to continue at a robust pace, and we think asset swaps could become more prevalent across the industry as business lines are realigned to focus on organizational strengths. These asset swaps could create more efficient and targeted businesses for large pharma that in turn could better utilize small cap biotech R&D programs.

- **We expect immuno-oncology to continue to attract enormous attention in both the scientific and investment worlds.** The first FDA filings for CARs should occur in 2016, and checkpoint inhibitors should continue on the developmental fast track. TCR programs could begin to emerge from the shadow of their CAR brethren. We expect combination strategies involving all of the above, and more, will continue to evolve.

Company	Symbol	Price (12/21)	Rating Prior	Rating Curr	PT
Clovis Oncology, Inc.	CLVS	$33.45	–	Neutral	$35.00
Epizyme, Inc.	EPZM	$17.34	–	Buy	$26.00
Kite Pharma, Inc.	KITE	$63.17	–	Buy	$90.00
Merrimack Pharmaceuticals, Inc.	MACK	$7.75	–	Buy	$16.00
NewLink Genetics	NLNK	$36.51	–	Buy	$62.00
OncoMed Pharmaceuticals, Inc.	OMED	$21.22	–	Buy	$45.00
Pfenex Inc.	PFNX	$12.00	–	Buy	$22.00
TESARO, Inc.	TSRO	$50.20	–	Buy	$67.00
Verastem Inc	VSTM	$1.84	–	Neutral	$2.00
ZIOPHARM Oncology, Inc.	ZIOP	$8.22	–	Neutral	$10.00

Source: Bloomberg and Mizuho Securities USA

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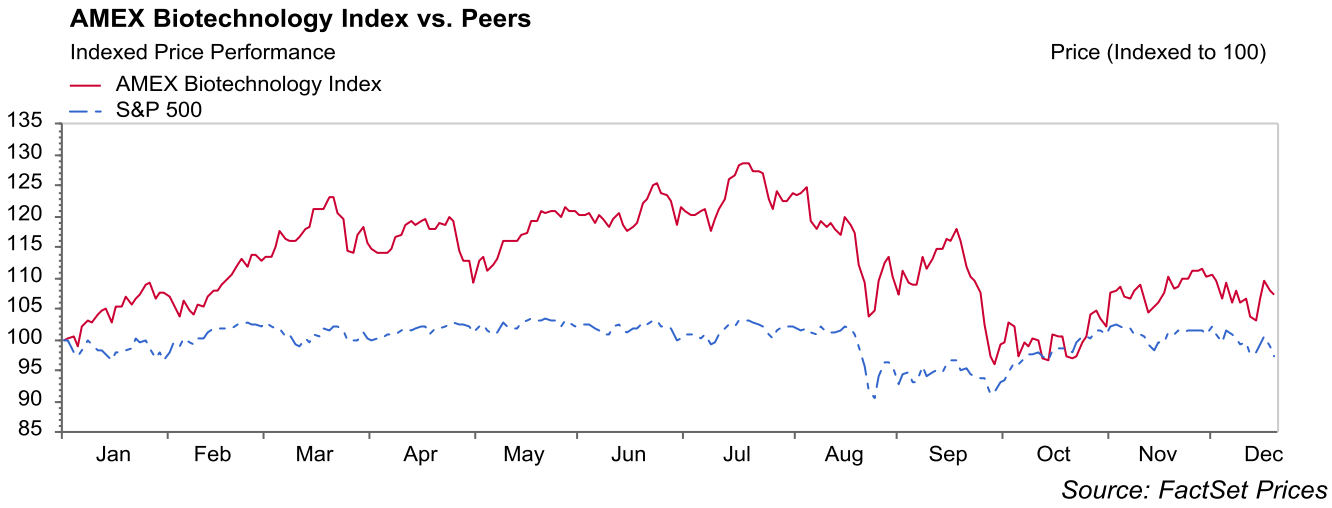
2015: It was the Best of Times, It was the Worst of Times

Biotech stocks posted a strong 1H15, with the AMEX Biotech Index (BTK) up 22% versus a flat S&P 500. The second half of 2015 brought a sharp correction, as the BTK fell 11%, versus the S&P down -2%, driven by negative attention on drug pricing as well as concerns about stretched valuations. Prices have recovered somewhat from the late September lows (Figures 1). Despite the 2H swoon, the BTK has outpaced the S&P 500 YTD.

Figure 1. BTK vs. S&P 500



Source: FactSet Prices

In our coverage universe, only PFNX, ZIOP, TSRO and ZIOP are up YTD (Figure 2). For PFNX, a $340mm deal with Hospira (Now part of PFE, Not Rated) for PFNX's lead biosimilar program drove 1H strength. Excitement around the potential of CAR T cell therapy has driven KITE's 2015 success. TSRO saw a successful Phase III trial and launch of its first product in 2015. ZIOP benefitted from an MD Anderson collaboration announced in January and, like KITE, the general excitement around engineered immune cells.

Figure 2. Biotech Coverage Price Changes, 2015

	Rating	1H % change	2H % change	YTD change
PFNX	Buy	170%	-38%	67%
ZIOP	Netural	137%	-32%	62%
TSRO	Buy	58%	-15%	35%
KITE	Buy	6%	4%	10%
OMED	Buy	3%	-6%	-2%
NLNK	Buy	11%	-18%	-8%
EPZM	Buy	27%	-28%	-8%
MACK	Buy	9%	-37%	-31%
CLVS	Neutral	57%	-62%	-40%
VSTM	Netural	-18%	-76%	-80%

Source: FactSet.

Political Headwinds Continue, for Now

Finally, after all the media focus, all the poll tracking, all the pundit arguments and rollicking televised debates…we're still 11 months away from the election. We expect drug pricing to continue to be in the crosshairs of stump speeches and candidate tweets. The arrest of a certain U.S. biopharma CEO provides an interesting topic around the watercooler, but we think the rhetoric around drug pricing is likely to remain a headwind for the biopharma industry. While we expect pricing to remain a headwind - at the least a headline risk - we also know how fickle political attention can be today. Any number of other topics can quickly supplant drug pricing if it makes poll numbers go up, potentially easing the pressure on drug companies. A continued focus on pricing could push pharma companies to push alternative pricing models, such as "pay-for-performance", into the limelight.

We Expect Small Cap Biotech to Continue to Fill Out Larger Cap Pipelines

We expect big pharma to remain on the hunt for assets to bolster growth and plug holes in their pipelines. There were expectations for GILD (Not Rated) to pull the trigger on a sizeable deal in 2015. Instead, they held their fire and their cash hoard grew heading into 2016 (approximately $25bn at the end of 3Q).

We think asset swaps could become more prevalent across the industry as business lines are realigned to focus on organizational strengths. GSK (Not Rated) swapped its oncology business for most of NVS' (Not Rated) vaccines business, but remains dedicated to building a cancer business. Sanofi (SAN-FR-Not Rated) is swapping its animal health business for Boehringer Ingeleheim's (Private) consumer business. These asset swaps could create more efficient and targeted businesses for large pharma that in turn could better utilize small cap biotech R&D programs.

We Expect Immuno-oncology to Continue to See Huge Attention

We expect immuno-oncology strategies to continue to attract enormous attention in both the scientific and investor worlds. The first FDA filings for chimeric antigen receptors (CAR) should be made in 2016, and checkpoint inhibitors such as PD-1 should continue to be on the developmental fast track, expanding to newer targets like TIM-3, LAG-3 and IDO. T cell receptor (TCR) programs should begin to emerge from the shadow of their CAR brethren in 2016, potentially generating the significant solid tumor efficacy so far lacking from CARs. Overall, we expect combination strategies that attack the tumor from multiple points using multiple modalities to continue to emerge.

What to Look For in 2016: CLVS

- June 28, 2016- New PDUFA date for rociletinib
- ASCO 2016 (June 3-7)- Data for rociletinib in 1st line versus erlotinib; Lucitanib data
- 2Q16- NDA filing for rucaparib

June is lining up to be a significant month for CLVS. The new PDUFA date for rociletinib was set for June 28, 2016, approximately three months after the original March 30 date. While the extension can be viewed as a positive in that the FDA is continuing to review the submission, we remain very cautious. The biggest downside risk is the FDA issuing a Complete Response Letter if they feel there is a lack of data to support either a 500mg or 625mg approval. On the positive side, the drug could still get approved, perhaps even before the new PDUFA date. Even with approval, however, it appears, based on the response data CLVS has submitted for the approval, that rociletinib's label could be substantially inferior to AZN's (Not Rated) Tagrisso. According to CLVS, confirmed response rates were 28%-37%, about 20-30% below Tagrisso's label (57%-61%). A nine-month duration of response is also lower than Tagrisso's 12.4 months. Additional competition is also at hand, with Boehringer Ingelheim announcing its own T790M lung cancer candidate, BI 1482694 (HM61713), received the FDA's Breakthrough Therapy designation. Objective responses (OR) were seen in 62% of patients, including 46% confirmed, versus CLVS' confirmed rate of 28-37%. CLVS could still see benefit from its side effect profile- Boehringer reported diarrhea rates of 55% (CLVS 33%) and rash (38%), versus less than 10% for CLVS.

Another important June catalyst for CLVS will be ASCO in early June. There, we expect initial data from the TIGER-1 study of rociletinib versus erlotinib in 1st line EGFR-positive NSCLC. AZN has presented its own 1st line data, most recently at World Lung, which showed Tagrisso ORR of 75% and 72% of patients at 12-month PFS. Also at ASCO, we expect CLVS to show initial lucitanib data in breast cancer.

We may also see updated data for CLVS' PARP inhibitor rucaparib in relapsed ovarian cancer, and we still expect an FDA filing by mid-2016.

What to Look for in 2016: EPZM

- 2016- U.S. IND
- Mid-2016- Initial Phase II NHL data
- 2H16- Phase II adult INI-1 negative data
- 2H16- Phase I pinemetostat pediatric data

We think the lack of an IND for U.S. trials of tazemetostat has been off-putting for investors. We expect EPZM to secure that IND and begin U.S. trials in 2016, which could remove the overhang and increase EPZM's appeal. We believe EPZM is an overlooked stock that has the potential to sneak up on investors with initial Phase II data for tazemetostat in NHL in mid-2016. The Phase II trial is a five-arm European trial as monotherapy in DLBCL and FL patients, stratified by EZH2 status, and for DLBCL patients, cell of origin (GC and non-GC). Should the EZH2-mutant arms produce solid results, the Phase II data alone could potentially support an NDA filing for that setting, given the lack of standard-of-care. All arms of the trial have a futility analysis. Beyond NHL, later in 2016 we could see initial Phase II data for INI-1 negative solid tumors and synovial sarcoma, as well as an update on the preclinical candidates in the GSK collaboration.

What to Look for in 2016: KITE

- YE 2016- KTE-C19 BLA filing
- 2H 2016- ZUMA-1 data update (Phase I update, initial Phase II data) and ZUMA-2 data
- Mid-to-2H 2016- TCR data

KITE could file its BLA for KTE-C19 by the end of 2016. We think this puts it slightly behind NVS (Not Rated), but ahead of JUNO (Not Rated) in the filing race, although KITE will be in NHL, while NVS and JUNO file in ALL, we believe. We expect an update of Phase I data from the ZUMA-1 trial, as well initial data from the Phase II portion potentially in mid-2016. We could also see initial data from the other ZUMA trials- ZUMA-2 (MCL); ZUMA-3 (adult ALL) and ZUMA-4 (pediatric ALL).

While CAR therapies have garnered the lion's share of attention in both the clinical and investment world, we expect to see a substantial increase in focus on TCR therapies. KITE and its NCI collaborators have four TCR programs in the clinic (NY-ESO-1; MAGE A3; MAGE A3/A6 and HPV-16 E6), focused on solid tumors- the tumor type that needs to be cracked in order to provide support to long term

valuations. With FDA submissions getting closer, we'll also shift our focus to the commercialization strategies: What will the selling model? Will cancer centers use multiple CAR therapies? How will reimbursement work? Have manufacturing logistics been addressed? All these questions, and more, will need to be answered sooner rather than later.

What to Look for in 2016: MACK

- 1H16- ONIVYDE launch
- 2016- ONIVYDE data in glioblastoma, pediatric sarcoma, and breast cancer
- 2H16- MM-121 NSCLC Phase II data (comb w/ doc/pem, 2nd/3rd line, HRG+); MM-121 partnership

The launch and sales ramp of ONIVYDE should be a focal point for MACK in 2016. While drug launches can often introduce periods of volatility for the stock, we are positive on the drug's prospects. ONIVYDE is the only drug approved for pancreatic patients that progress following gemcitabine therapy- representing a U.S. market opportunity of approximately 20,000 patients. There is no standard-of-care for 2nd and 3rd line patients. MACK has also initiated a broad development strategy for MM-398, which could produce initial data in glioblastoma, pediatric sarcoma and breast cancer in 2016.

Beyond '398, a partnership for MM-121 has not yet materialized in 2015, so we now look for one in 2016. We feel the partnership has now become an overhang for the stock, so an announcement of solid terms for MACK could remove the overhang as well as be seen as a positive from a financial point-of-view would trigger the advancement of the breast cancer program. Phase II data for '121 in NSCLC (2nd/3rd line, heregulin-positive, in combination with chemo) should come in 2H16,

What to Look for in 2016: NLNK

- 1H16- Phase III IMPRESS final analysis (combo with gemcitabine vs. gem alone) resected pancreatic cancer
- Mid 2016- Phase III PILLAR data
- Mid-to-2H16- Phase II data for HyperAcute lung, melanoma programs; Indoximod breast, GBM data
- 2016- GDC-0919 data update

NewLink could produce the biggest fireworks show in 2016. We could potentially see two Phase III readouts from NLNK in 1H16- the IMPRESS and PILLAR trials of algenpantucel-L in pancreatic cancer. We think the trials have a negative opinion around them overall, given the bleak historical results of vaccine-like therapies for cancer. However, with AMGN (Not Rated) recently gaining FDA approval for its

IMLYGIC oncoloytic viral therapy for melanoma, perhaps that's a signal of better times ahead for this treatment strategy.

Investors were also put off by the inability of NLNK to change the statistical analysis plan for the interim analysis in 2015 (from proportional hazards log-rank to weighted log-rank). There is concern that traditional statistical analysis methods do not do a good job teasing out the delayed action of immuno-oncology agents versus quicker-acting traditional therapies. However, we note that the FDA was concerned with allowing NLNK to implement a change while the overall death rates in the trial were known, and how that might also affect the PILLAR trial. Though it was unable to amend the interim analysis, NLNK does have flexibility for the final analysis, and subset analysis is also included in the study protocol. The IMPRESS trial's blended median overall survival is now around 30 months, from the time of surgical resection. Meanwhile, historical OS in surgically resected pancreatic patients is estimated to be in the low 20's. This divergence could be a signal that the treatment arm is surviving for a significantly longer time than the control arm. We also believe we could see data from NLNK's other HyperAcute candidates in 2016, which have been largely ignored.

According to commentary by NLNK, the collaboration with Roche/Genentech appears to have significant, front-end weighted milestones larger than industry norms. These have not been disclosed in detail but could provide investors with a positive surprise if they are realized. For a milestone comparison, MACK got $15mm from Baxalta (BXLT- Not Rated) on the initiation of a front line pancreatic cancer trial.

What to Look for in 2016: OMED

- Mid-2016-First Phase II data readout: ALPINE study (tarextumab in pancreatic cancer); potential YOSEMITE and DENALI Phase II data 2H16
- 1Q16- Demcizuamb safety analysis (linked to CELG milestone)
- Mid-2016-Phase I data for ipafricept, vantictumab, DLL4/VEGF dual antibody and RSPO3

We're impressed by the scale of OMED's development program relative to its size- a $600mm market cap with 7 clinical programs and approximately 17 clinical trials ongoing. OMED has lined up impressive partnerships with Celgene (CELG), GSK (Not Rated) and Bayer (Not Rated), but that also leads to some bemoaning of the fact that virtually the entire pipeline has been partnered.

We expect the ALPINE study of tarextumab in pancreatic cancer to be the first of OMED's Phase II studies to read out, in mid-2016. We've seen a lot of Phase I data across OMED's programs, but this first Phase II data should be a significant catalyst for the stock, and include overall survival. The trial is powered to show a two to

three month survival advantage in 1st line combination with gem-Abraxane versus gem-Abraxane alone.

In 1Q16 OMED could receive a $70mm milestone payment from CELG (Not Rated) for a safety analysis in the demcizuamb program. We expect Phase I data for ipafricept, vantictumab, DLL4/VEGF dual antibody and RSPO3 in 1H16, and potentially YOSEMITE and DENALI Phase II data (demcizumab in pancreatic and NSCLC) in 2H16.

What to Look for in 2016: PFNX

- Mid-2016- Initiation of Phase III equivalence trial vs. Lucentis
- 2H16- Initiation of abbreviated pivotal program PF530 (Betaseron)
- 2016- FDA, CMS biosimilar regulations

With launch of PFNX's first biosimilar not expected until 2018, we'll be looking for them to execute on the fundamentals and continue to progress without any hiccups. An example of "hiccup": CHRS (Not Rated) disclosing an "anomaly" in their PK/PD study of pegfilgrasim (Neulasta) biosimilar CHS-1701.

We think industry-level developments, such as FDA guidance and state laws on interchangeability/substitution (i.e., automatically switching biosimilar for the branded drug at the pharmacy) will be important developments. We have already seen a somewhat negative decision by CMS to lump all biosimilars of a given drug together in a payment scheme.

Patent issues will also be a revolving issue, although we have gotten some clarity about the "Patent Dance" (it's optional, so far) and the related notification timing (notice of intent to commercialize must be given after approval, and can't start selling until six months after approval).

What to Look for in 2016: TSRO

- 1Q16- VARUBI launch, NDA submission for IV version
- 2Q16- Niraparib Phase III NOVA data; QUADRA data
- Niraparib FDA filing 2H16
- 1H16- Checkpoint inhibitor candidates enter the clinic

TSRO is our favorite Biotech stock for 2016. Like MACK, the launch and sales ramp of TSRO's first product, VARUBI, will be a point of interest.. However, only the oral version of the drug will be available at launch, which addresses approximately 20% of the market. We expect the FDA application for the IV version to be submitted in 1Q16, with approval/launch in 4Q16. We think VARUBI, for

treatment of chemotherapy induced nausea and vomiting (CINV) can readily be a $500mm product, with upside to $1bn. Management has a proven track record of commercializing drugs in this setting, having taken the drug ALOXI to market in a similar indication with MGI Pharma, later bought by Eisai for $3.9bn in 2008. In addition, VARUBI has already been included in NCCN guidelines, increasing physician familiarity and validation. While we have confidence in the commercialization given these points, the launch is likely to be overshadowed by the niraparib Phase III NOVA data and initial QUADRA data in 2Q16 and potential NDA filing in 2H.

TSRO pushed out the expected data analysis for the NOVA study from 4Q15 to 2Q16, as PFS events did not reach the threshold for an interim analysis in the non-germline BRCA cohort (non-gBRCA). Given the historical control assumptions, maintenance setting and 2:1 randomization, we interpreted the push out of the analysis as a positive sign that the niraparib arm was outperforming the control arm as expected. That said, we acknowledge that nothing can be definitively stated until the final results are released.

For background, NOVA is comparing niraparib versus placebo in the maintenance setting for platinum-sensitive ovarian cancer patients (at least 2 prior platinum therapies). Subjects are enrolled in one of two cohorts: those with germline BRCA mutations (gBRCA-mut), and those with non-gBRCA. The non-gBRCA cohort is further divided into HRD-positive and negative patients- a genomic biomarker. Each cohort is randomized 2:1 (niraparib:placebo) and independently powered at over 90% to detect a 4.5 month improvement in PFS versus placebo (Hazard Ratio of 0.5). The PFS assumption for the control (placebo) arm is 4.5 month. PFS in the non-gBRCA cohort will be analyzed first in the HRD-positive subset, and then, if that p-value<0.05, for PFS in the entire cohort. For the gBRCA cohort, only overall PFS will be assessed. The control assumptions in this trial are based on three maintenance ovarian cancer trials (n=590) where PFS was between four and five and a half months.

Beyond the NOVA analysis, we also expect initial data from the Phase II QUADRA trial of niraparib in fourth line or later ovarian cancer patients. The QUADRA trial is highly comparable to Lynparza's current approved indication, which should provide strong marketing message, assuming the data is positive (Lynparza showed an ORR of 34% in its label, median duration of therapy of 7.9 months).

We also expect to see more focus on TSRO's immuno-oncology program as it enters the clinic, with checkpoint inhibitors TSR-042 (anti-PD-1) and TSR-022 (anti-TIM-3) in the clinic potentially by mid-2016, and an anti-LAG-3 candidate potentially by year-end. These assets are very early, and the PD-1 is significantly behind others that are already commercialized and gaining momentum, such as KEYTRUDA and OPDIVO. However, we are seeing TIM-3 and LAG-3 emerge from PD-1's shadow in medical meetings, and we like that TSRO has all three in-house, making it easier to control development, steer combination usage and increase attractiveness to partners and/or acquirers.

What to Look for in 2016: VSTM

- 1Q16- Strategic update
- 1H16- Defactinib ovarian and NSCLC program updates
- 1H16- VS-5584 and 4718 data

VSTM has to regroup following the failure of its lead candidate defactinib in mesothelioma earlier in 2015. The company sits on approximately $120mm in cash and equivalents, so it could acquire a new asset. The cash balance, plus two early stage assets (VS-5584 and VS-4718) could be attractive to a potential acquirer. That said, we're staying on the sidelines as we await updates on a go-forward strategy, as well as data from the early-stage assets.

What to Look for in 2016: ZIOP

- 1Q16- Timeline updates
- ASCO 2016 (June 3-7)- CAR data updates

ZIOP's recent Corporate update in December highlighted a very broad development strategy featuring a multi-modality immuno-oncology platform: viral and non-viral gene transfer, autologous (patient-derived) and allogeneic (donor-derived) strategies; T cell and NK cell products, among several other platforms and targets. A trial involving a new version of the Sleeping Beauty technology is enrolling at MD Anderson.

We expect cancer treatment to continue to develop into a multi-faceted approach. While we like that ZIOP is going down this path as well, we remain on the sidelines until we see more significant clinical data from these early-stage programs. ZIOP appears well behind others like KITE in the engineered T cell space, and other companies are developing specialization in areas like TCR (i.e. Adaptimmune-ADAP, Not Rated). We hope to hear a more detailed outlook on timing of data from these programs and the pacing of trial initiations in the beginning of 2016. We stay on the sidelines as we await these updates.

Price Target Calculation and Key Risks

Clovis Oncology, Inc.

We apply both a discounted cash flow analysis and discounted P/E analysis to yield a price target of $35. Risks to our price target primarily include failures, delays or setbacks in clinical trials and competition, along with general and macroeconomic trends.

Epizyme, Inc.

Our 12-month price target of $26.00 is based on a combination DCF and discounted P/E analysis. Risks to our price target outside of clinical failure relate to 1) commercialization risk, 2) partnership risk and 3) pipeline risk.

Kite Pharma, Inc.

We derive our price target by applying both a discounted cash flow analysis and discounted P/E analysis to yield a price target of $90. Risks to our price target outside of clinical failure relate to 1) platform risk, 2) competitive risk and 3) commercialization risk.

Merrimack Pharmaceuticals, Inc.

We derive our price target by applying both a discounted cash flow analysis and discounted P/E analysis to yield a price target of $16. The primary risks surrounding Merrimack's stock relate to 1) failure to meet efficacy endpoints and unforeseen safety issues 2) setbacks in strategic and business development, as well as financing risk and 3) platform risk.

NewLink Genetics

Our 12-month price target of $62.00 is based on a combination of DCF and discounted P/E analysis. Risks to our price target outside of clinical failure relate to 1) platform risk, 2) competitive risk, and 3) commercialization risk.

OncoMed Pharmaceuticals, Inc.

Our 12-month price target of $45.00 is based on a combination DCF and discounted P/E analysis. Risks to our price target include negative clinical data, competition and financing.

Pfenex Inc.

Our 12-month price target of $22.00 is based on a combination DCF and discounted P/E analysis. The primary risks surrounding Pfenex's stock outside of clinical failure relate to: 1) commercialization; 2) competition and patent / regulatory; and 3) partnership risk.

TESARO, Inc.

Based on our DCF and discounted earnings model, we derive a 12-month price target of $67. Risks to our price target include negative clinical data, financing, regulatory hurdles and competition, in addition to general and macroeconomic trends.

Verastem Inc

Our 12-month price target of $2 is based on a DCF analysis, incorporating a WACC of 15%, 10% probabilities of success and long term growth of 5%. The primary risks surrounding Verastem's stock relate to 1) failure to meet efficacy endpoints and unforeseen safety issues 2) competition, and 3) business development failure.

ZIOPHARM Oncology, Inc.

Our 12-month price target of $10 is based on a on a combination DCF and discounted P/E analysis. The primary risks surrounding ZIOPHARM's stock relate to 1) partnership risk, being so closely aligned with Intrexon, 2) pipeline breadth risk, potentially spreading efforts too thin, and 3) reliance on synthetic biology that is largely unproven commercially.

Companies Mentioned (prices as of 12/21)

Amgen Inc (AMGN- Not Rated)
Celgene Corp (CELG- Not Rated)
Novartis (NVS- Not Rated)
Baxalta Inc (BXLT)
Gilead (GILD- Not Rated)

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Hold (Neutral)	52.00%	25.27%
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