

BIND Therapeutics (BIND)

SMALL & MID CAP RESEARCH

Q3 Results: No Surprises, Ph2 On Track



Rating	OUTPERFORM* [V]
Price (04 Nov 13, US\$)	13.00
Target price (US\$)	21.00 ¹
52-week price range	15.31 - 12.66
Market cap. (US\$ m)	208.83
Enterprise value (US\$ m)	140.78

*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

¹Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

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- **BIND reported Q3 net loss of (\$7.4M) on revenue of \$4.6M** vs. consensus of (\$8.9M) on revenue of \$1.9M. We had estimated net loss of (\$9.2M) on revs of \$2.1M. The revenue upside was driven by the timing of revenue recognition (not new cash inflows) and expenses were similarly impacted by one-time stock option expenses related to the IPO.
- **Phase II enrollment is going well; timing for data unchanged:** BIND reported that enrollment in the BIND-014 Phase II prostate cancer study is proceeding ahead of forecast and the lung cancer trial is on plan. Both are expected to have data in H2:14, which is unchanged from prior guidance. A broad entry criteria and limited competition for chemotherapy options in prostate cancer is the reason for more rapid recruitment, while the lung study faces more competition for patients given the large number of drugs in development for second line non-small cell lung cancer.
- **Reiterate Outperform Rating and a \$21 Target Price:** Our positive view is based on the large market opportunity for the lead program (BIND-014) in cancer and the broad applicability of the platform for targeted delivery of multiple drugs across indications.
- **Changes to model:** Our revenue estimate is unchanged for the year, despite the Q3 upside. Expenses are slightly higher. The difference in EPS is driven by share count changes.
- **\$21 target:** Our TP includes \$17 for BIND-014 and \$4 for the partnerships. For BIND-014, we assume a 65% probability of success and a 2018 launch.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US\$)	-1.98	-4.43	-2.07	-0.18
Prev. EPS (US\$)	—	-2.09	-2.11	-0.09
P/E (x)	-6.6	-2.9	-6.3	-71.5
P/E rel. (%)	-39.2	-18.7	-44.3	-553.8
Revenue (US\$ m)	1.0	13.4	17.4	72.4
EBITDA (US\$ m)	-17.5	-23.5	-34.4	-2.4
OCFPS (US\$)	-1.78	-2.90	-2.03	0.04
P/OCF (x)	—	-4.5	-6.4	305.8
EV/EBITDA (current)	-11.0	-8.2	-5.6	-80.3
Net debt (US\$ m)	-2	-68	-141	-140
ROIC (%)	-1,028.15	1,410.10	-999.14	-69.70
Number of shares (m)	16.06	IC (current, US\$ m)		1.81
BV/share (Next Qtr., US\$)	51.3	EV/IC (x)		-31.5
Net debt (Next Qtr., US\$ m)	-76.0	Dividend (current, US\$)		—
Net debt/tot cap (Next Qtr., %)	-105.9	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

DISCLOSURE APPENDIX CONTAINS IMPORTANT DISCLOSURES, ANALYST CERTIFICATIONS, INFORMATION ON TRADE ALERTS, ANALYST MODEL PORTFOLIOS AND THE STATUS OF NON-U.S. ANALYSTS. US Disclosure: Credit Suisse does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the Firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision.

Portfolio Manager Summary

BIND's primary asset is a wholly owned Accurin drug-delivery platform. The lead program, BIND-014, is a Phase II asset that has demonstrated safety/efficacy in Phase I trials. BIND-014 is designed as a controlled release formulation of docetaxel that is expected to have a better safety/efficacy profile compared to docetaxel alone.

BIND-014 is relatively derisked in the sense that the active drug (docetaxel) is an established treatment of multiple cancers; thus, the drug can utilize the simpler 505(b)2 regulatory pathway for gaining approval. BIND-014 will need to show a significant clinical advantage over generic docetaxel in order to gain widespread market acceptance.

BIND has several key value-inflection catalysts expected in the next one to three years.

- **Data from Phase II Studies** in metastatic, castration resistant prostate cancer patients (mCRPC), and second-line NSCLC patients are expected in H2:14.
- **IND Filings for Partnered Programs** are expected in late 2014/2015. Moving forward with these programs would be a vote of confidence from big pharma.
- **Target Selection from Proprietary Preclinical Programs Expected in 2014:** Additional data from new programs could demonstrate broader utility of technology.

Exhibit 1: BIND Pipeline

Drug	Indication	Stage	Partner
BIND 014 (PSMA targeted docetaxel)	NSCLC and mCRPC	Phase II	Proprietary
Solid Tumor Accurin	Solid Tumor	Pre-clinical	Proprietary
Hematologic Cancer Accurin	Hematologic Cancer	Pre-clinical	Proprietary
Oncology kinase inhibitor	N/A	Pre-clinical	Amgen
Targeted therapies	N/A	Pre-clinical	Pfizer
Oncology kinase inhibitor	N/A	Pre-clinical	AstraZeneca

Source: Company data, Credit Suisse research.

Exhibit 2: BIND News Flow

Timing	Expected News Flow	Program
Q1:14	Target selection	Solid Tumor Accurin
H2:14	Phase II data in NSCLC and mCRPC	BIND-014
Q4:14	Target selection	Hematologic Cancer Accurin
YE:14	IND submission	Partnered program
2015	IND submission	2nd BIND product
2015	IND enabling tox studies	3rd BIND product

Source: Company data, Credit Suisse estimates.

Investment Positives

- **Technology for Targeted Cancer Drug Delivery:** BIND wholly owns its proprietary platform that can be modified for the delivery of different drugs using different targeting ligands. The program has broad utility in delivery of cancer drugs and potentially other diseases, such as cardiovascular.
- **Lead Program Addresses Large, Established Markets:** BIND-014 is a nanoparticle delivery system for docetaxel, the standard of care for treating several major cancers (e.g., NSCLC, breast, prostate). BIND-014 is designed to have a better safety/efficacy

profile than generic docetaxel. BIND-014 could have fewer adverse events, particularly neuropathy and fatigue, which currently limit more widespread use of docetaxel.

- **Management Has Extensive Experience Developing Nanoparticle/ Reformulation Drugs:** Management has brought to market drugs at Abraxis, Alkermes, and Sequus.
- **Lower Risk Path to Market for the Lead Program (BIND-014):** BIND-014 is taking the 505(b)2 regulatory pathway, typically used for reformulations of approved drugs, which makes it less risky than approval for a new chemical entity (NCE). This pathway allows BIND to use well established safety data from docetaxel in its application. If approved, physician familiarity with docetaxel could drive early uptake, as docetaxel is already the standard of care for several major cancers.
- **Ongoing and Planned Phase II Trials Are Likely to Reduce the Risk of BIND-014 and the Overall Platform:** Data from two large single-arm studies should provide a clear view on the efficacy and safety advantages of BIND-014, support a move to Phase III, and substantially derisk the platform.
- **Three Pharma Deals Validate the Technology Platform:** Amgen and Pfizer both have an option on cancer drug delivery programs. AstraZeneca has already exercised an option with BIND for delivery of an AZ proprietary kinase inhibitor. Funding for these programs is an important source of nondilutive funding.
- **Potential Barriers to Entry for Generic Competitors:** While other nanoparticle technologies may be applied to docetaxel, BIND has significant IP protection for its Accurin platform, and the regulatory pathway for a generic nanomedicine is not as straightforward as a small-molecule generic.

Investment Risks

- **Early Stage Technology with Limited Clinical Data:** Phase I data indicated that BIND-014 is safe and has clinical activity. However, we have no direct head-to-head comparison of BIND-014 with docetaxel, so there is a risk that BIND-014 may not be clinically superior. The comparison with docetaxel will affect whether or not the drug is approved and gains favorable reimbursement status and market acceptance.
- **Ongoing and Planned Phase II Trials Are Uncontrolled:** The lack of a control arm in the BIND-014 trials (versus historical docetaxel results) may increase the risk in Phase III.
- **Risks Around Safety:** In theory, BIND-014 should have more favorable safety than docetaxel due to its multiple targeting mechanisms. However, the lower MTD of BIND-014 (compared to docetaxel) and its longer circulation time may increase some toxicities.
- **Risks Around Reimbursement and Market Acceptance:** There are clear risks around market potential and pricing if BIND-014 does not show a significant clinical and/or safety benefit over docetaxel.
- **Risks Around Newer Therapeutic Options:** New hormonal regimens for CRPC will likely push back chemo in treatment line. Targeted agents are in trials for indications in which docetaxel is currently used, particularly in NSCLC.
- **Financial Risk:** Our model is highly dependent on signing a partnership for BIND-014 and the receipt of early partner milestones.

Target Price—\$21/Share

Our valuation is supported by a DCF using probability-weighted sales estimates for BIND-014 modeled through 2028 (\$17/share) and a DCF analysis of the three partnerships (\$4/share). We assume a 65% probability of success for BIND-014 in three main docetaxel markets (e.g., NSCLC, mCRPC, and an additional indication) and a 12% probability of success for partnered programs (earlier milestones have higher probability). We model a commercial launch of BIND-014 in 2018. We use a 38% tax rate and a 12% discount rate.

The following are the biggest levers in our valuations.

- (1) **Probability of Success:** We use 65% probability of success for BIND-014 in three main docetaxel markets. (See Exhibit 3). We assign a relatively high probability of success for a Phase II program, given the active agent is well established.
- (2) **Pricing of BIND-014:** We assume that BIND-014 shows a significant safety and efficacy benefit over docetaxel to justify premium pricing (\$2,500/month).
- (3) **Timing of U.S. and EU Approvals:** We assume U.S. and ex-U.S. launches in 2018 for BIND-014.
- (4) **We Assume BIND Enters a Partnership for ex-U.S. Rights and Receives a Royalty on Future Sales:** We have modeled probability-adjusted clinical and regulatory milestones for BIND-014 and a tiered royalty on future global sales.
- (5) **We Assume Probability-Adjusted Milestones and Royalties from the Three Partnership Programs:** We assume that one drug from each program reaches the clinic in 2015 and enters the market in 2026. All milestones and sales estimates are probability adjusted. We assume a 12% probability of success for approval, and we model \$500M peak sales.

Exhibit 3: Probability of Success Valuation Matrix (Includes \$4 for Partnerships)

Price target		POS	NPV/share
BIND-014	\$17	50%	\$13
Partnerships	\$4	55%	\$15
Total	\$21	60%	\$18
		65%	\$21
		70%	\$22
		75%	\$25
		80%	\$28

Source: Company data, Credit Suisse estimates.

Exhibit 4: Sales Model for BIND-014

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
US MODEL											
mCRPC Addressable Patients	23,185	23,881	24,597	25,335	26,095	26,878	27,685	28,515	29,371	30,252	31,159
NSCLC Addressable Patients	34,488	35,523	36,589	37,686	38,817	39,982	41,181	42,416	43,689	45,000	46,350
Additional Indication	34,778	35,822	36,896	38,003	39,143	40,317	41,527	42,773	44,066	45,378	46,739
Penetration	5%	20%	30%	33%	35%	38%	38%	38%	38%	38%	38%
Treated- mCRPC	1,159	4,776	7,379	8,234	9,133	10,079	10,382	10,693	11,014	11,344	11,685
Treated- NSCLC	1,724	7,105	10,977	12,248	13,586	14,993	15,443	15,906	16,383	16,875	17,381
Treated other	1,739	7,164	11,069	12,351	13,700	15,119	15,573	16,040	16,521	17,017	17,527
Price/ month	\$2,500	\$2,625	\$2,756	\$2,894	\$3,039	\$3,191	\$3,350	\$3,518	\$3,694	\$3,878	\$4,072
Revenue- mCRPC	\$20	\$88	\$142	\$167	\$194	\$225	\$243	\$263	\$285	\$308	\$333
Revenue- NSCLC	\$13	\$56	\$91	\$106	\$124	\$144	\$155	\$168	\$182	\$196	\$212
Revenue- other	\$17	\$75	\$122	\$143	\$167	\$193	\$209	\$226	\$244	\$264	\$285
Total- US	\$51	\$219	\$355	\$416	\$485	\$562	\$607	\$657	\$710	\$768	\$831
Total ROW	\$0	\$66	\$178	\$270	\$363	\$505	\$607	\$657	\$710	\$768	\$831
ROW Royalties	\$0	\$7	\$18	\$27	\$37	\$53	\$69	\$76	\$84	\$93	\$102
Manufacturing profit (20% mark up)	\$0	\$2	\$4	\$6	\$9	\$12	\$15	\$16	\$17	\$18	\$20
Total BIND-014 revenue	\$51	\$227	\$377	\$450	\$531	\$627	\$691	\$749	\$812	\$879	\$953
Probability Adjusted Revenue	\$33	\$148	\$245	\$292	\$345	\$408	\$449	\$487	\$527	\$572	\$619

Source: Company data, Credit Suisse estimates.

Exhibit 5: BIND Earnings Model

	Q1:13A	Q2:13A	Q3:13A	Q4:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues														
BIND-014 US sales										50.6	218.9	355.2	416.1	484.7
BIND-014 ex-US royalties and mfg. rev											8.1	22.0	33.7	46.2
Partnering, grants, milestones	1.5	2.8	4.6	4.6	13.4	17.5	72.4	19.2	38.4	39.0	10.0	25.5	10.0	10.0
Total Revenues	1.5	2.8	4.6	4.6	13.4	17.5	72.4	19.2	38.4	89.6	237.1	402.7	459.9	540.9
Expenses														
Research and development	5.7	6.0	5.3	8.0	25.0	42.0	63.0	66.8	70.8	75.0	78.8	82.7	86.9	91.2
Sales, general, administrative	2.0	2.4	6.3	2.7	13.4	11.5	13.5	18.2	34.1	105.8	111.1	116.6	122.5	128.6
Cost of goods										6.1	26.3	42.6	49.9	58.2
Royalty expense										1.5	6.6	10.7	12.5	14.5
Total Operating Expenses	7.6	8.4	11.6	10.7	38.4	53.5	76.5	85.0	104.9	188.4	222.7	252.6	271.7	292.5
Operating income (loss)	(6.1)	(5.6)	(7.1)	(6.2)	(25.0)	(36.1)	(4.1)	(65.8)	(66.5)	(98.8)	14.4	150.1	188.1	248.4
Total Other Income (Expense)	(0.2)	(0.3)	(0.3)	(0.1)	(0.8)	(0.2)	(0.1)	0.8	0.6	0.4	0.8	1.0	1.2	1.5
Pre Tax Income	(6.3)	(5.9)	(7.4)	(6.2)	(25.8)	(36.3)	(4.2)	(65.0)	(65.9)	(98.4)	15.2	151.1	189.3	249.9
Income tax													66.3	87.5
Net Income	(7.6)	(7.3)	(8.3)	(6.2)	(29.5)	(36.3)	(4.2)	(65.0)	(65.9)	(98.4)	15.2	151.1	123.1	162.4
EPS - basic (proforma)														
EPS - diluted (proforma)	(\$2.90)	(\$2.68)	(\$2.70)	(\$0.39)	(\$5.06)	(\$2.07)	(\$0.19)	(\$2.24)	(\$2.24)	(\$3.30)	\$0.50	\$4.91	\$3.94	\$5.13
	(\$2.90)	(\$2.68)	(\$2.70)	(\$0.39)	(\$5.06)	(\$2.07)	(\$0.18)	(\$2.24)	(\$2.24)	(\$3.30)	\$0.45	\$4.39	\$3.52	\$4.57
Shares outstanding - basic (proforma)	2.17	2.21	3.08	15.87	5.83	17.57	22.47	28.98	29.41	29.86	30.30	30.76	31.22	31.69
Shares outstanding - diluted (proforma)	2.17	2.21	3.08	15.87	5.83	17.57	23.29	28.98	29.41	29.86	33.91	34.44	34.97	35.51

Source: Company data, Credit Suisse estimates

Key Modeling Assumptions

We model first BIND-014 sales in 2018 and peak share in 2023. Our model projects \$560M in U.S. sales at a peak penetration of approximately 38%; ex-U.S. sales in that year are estimated at \$500M. Sales continue to grow through price and market growth through 2028. Our model starts with a projection of the total docetaxel-treated population and an estimated penetration rate for BIND-014. Several of these assumptions have built in conservative estimates.

- **Pricing:** We assume initial pricing of \$2,500 per month and a cost of goods of 12%. This is slightly higher than the company's estimated manufacturing costs of roughly

\$87/vial and 3 vials/month, which adds conservatism to our estimate. This pricing is in-line with other branded cancer therapeutics.

- **Market Size:** We assume BIND-014 receives approval in three indications that have roughly 20,000-30,000 addressable patients each. Our estimate of addressable patients is based on patients currently treated with docetaxel; we assume a maximum penetration rate of 38%. We do not assume that BIND-014 expands the market size for treatment with docetaxel. Market expansion represents upside.
- **Risk-Adjusted Market Model:** We assume a 65% probability of success. While this probability of success is relatively high for a Phase II asset, we believe the program has lower risk due to the use of docetaxel as the active agent. We believe that our probability of success accounts for the risk of a poor launch (e.g., the drug gaining approval but then running into reimbursement and market acceptance difficulties).

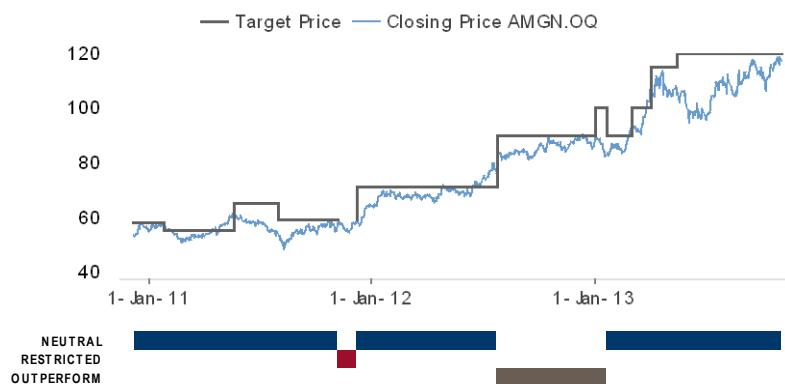
Companies Mentioned (Price as of 05-Nov-2013)**Amgen Inc.** (AMGN.OQ, \$117.28)**AstraZeneca** (AZN.L, 3291.5p)**BIND Therapeutics** (BIND.OQ, \$13.0, OUTPERFORM[V], TP \$21.0)**Pfizer** (PFE.N, \$31.26)**Disclosure Appendix****Important Global Disclosures**

Jason Kantor, PhD, Ravi Mehrotra PhD and Lee Kalowski each certify, with respect to the companies or securities that the individual analyzes, that (1) the views expressed in this report accurately reflect his or her personal views about all of the subject companies and securities and (2) no part of his or her compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

3-Year Price and Rating History for Amgen Inc. (AMGN.OQ)

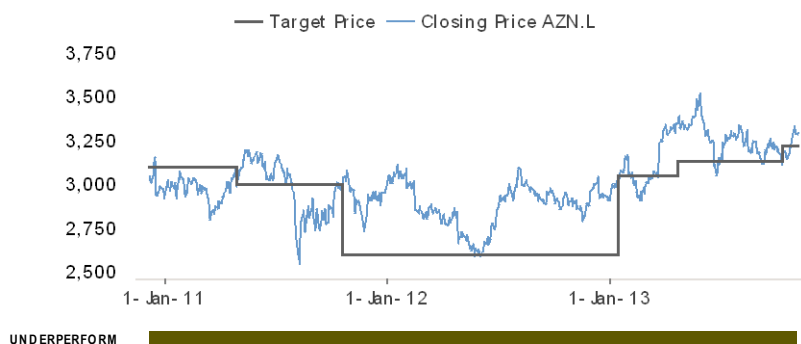
AMGN.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
06-Dec-10	53.39	58.00	N *
25-Jan-11	57.16	55.00	
20-May-11	60.89	65.00	
01-Aug-11	53.77	59.00	
07-Nov-11	58.43		R
08-Dec-11	58.41	59.00	N
09-Dec-11	58.59	71.00	
25-Jul-12	77.96	85.00	O
26-Jul-12	79.30	90.00	
03-Jan-13	88.59	100.00	
22-Jan-13	83.29	90.00	N
04-Mar-13	92.73	100.00	
04-Apr-13	105.90	115.00	
17-May-13	105.63	120.00	

* Asterisk signifies initiation or assumption of coverage.

**3-Year Price and Rating History for AstraZeneca (AZN.L)**

AZN.L	Closing Price	Target Price	
Date	(p)	(p)	Rating
07-Dec-10	3027.50	3100.00	U
29-Apr-11	2990.00	3000.00	
19-Oct-11	2981.00	2600.00	
21-May-12	2654.50		*
22-May-12	2650.00		*
17-Jul-12	2953.50	2600.00	U
14-Jan-13	3030.00	3050.00	
22-Apr-13	3350.00	3130.00	
10-Oct-13	3133.00	3220.00	

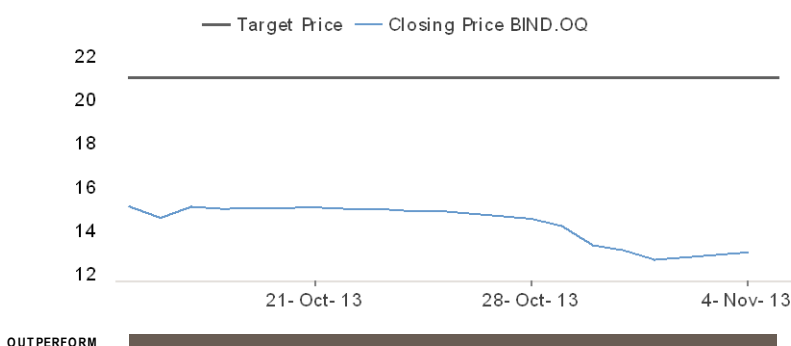
* Asterisk signifies initiation or assumption of coverage.



3-Year Price and Rating History for BIND Therapeutics (BIND.OQ)

BIND.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
15-Oct-13	15.10	21.00	O *

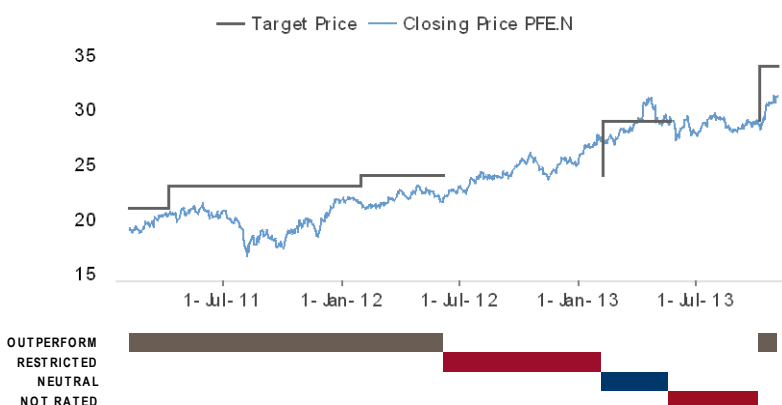
* Asterisk signifies initiation or assumption of coverage.



3-Year Price and Rating History for Pfizer (PFE.N)

PFE.N	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
07-Feb-11	19.04	21.00	O
08-Apr-11	20.46	23.00	
31-Jan-12	21.40	24.00	
07-Jun-12	21.94		R
07-Feb-13	26.96	29.00	N
22-May-13	29.30		NR
08-Oct-13	28.24	34.00	O *

* Asterisk signifies initiation or assumption of coverage.



The analyst(s) responsible for preparing this research report received Compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities

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Outperform (O) : The stock's total return is expected to outperform the relevant benchmark* over the next 12 months.

Neutral (N) : The stock's total return is expected to be in line with the relevant benchmark* over the next 12 months.

Underperform (U) : The stock's total return is expected to underperform the relevant benchmark* over the next 12 months.

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Market Weight : The analyst's expectation for the sector's fundamentals and/or valuation is neutral over the next 12 months.

Underweight : The analyst's expectation for the sector's fundamentals and/or valuation is cautious over the next 12 months.

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Global Ratings Distribution

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Neutral/Hold*	41%	(49% banking clients)
Underperform/Sell*	15%	(40% banking clients)
Restricted	3%	

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Price Target: (12 months) for BIND Therapeutics (BIND.OQ)

Method: Our \$21 target price for BIND is based on DCF (discounted cash flow) using probability-weighted sales estimates for BIND-014 modeled through 2028 (\$17 per share) and a DCF analysis of three partnerships with major pharmaceutical companies (\$4 per share). We estimate a 65% probability of success for BIND-014 and a 15% probability of success for partnered programs. We model a commercial launch of BIND-014 in 2018. We use a 38% tax rate and a 12% discount rate.

Risk: Risks to our \$21 target price for BIND are (1) unexpected negative efficacy or safety result in ongoing Phase II BIND-014 study, (2) regulatory risk of potential approval for BIND-014, (3) execution risk in signing a potential partner for BIND-014 and/or launch and marketing of BIND-014, if approved, (4) failure of its partners to move forward with current programs, and (5) financing risk.

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See the Companies Mentioned section for full company names

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