Ardelyx, Inc. (ARDX)

Phase IIa Tenapanor Results in CKD Miss Primary Endpoint

MARKET OUTPERFORM | Price: $10.91 | Target Price: $24.00

MARKET DATA

Price	$10.91
52-Week Range:	$10.40 - $35.48
Shares Out. (M):	18.5
Market Cap ($M):	$201.8
Average Daily Vol. (000):	53.0
Cash (M):	$107
Cash/Share:	$5.81
Enterprise Value (M):	$97
Float (M):	15.4
LT Debt (M):	$0
Short Interest:	1.8%

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$8.6	$13.3	$14.0
	2Q	$9.1	$14.0	$34.7
	3Q	$7.6	$34.7	$40.6
	4Q	$6.3	$40.6	$102.6
	FY	**$31.6**	**$102.6**	**$124.2**
EPS	1Q	($0.23)	$0.05	$0.01
	2Q	$0.18	$0.01	$1.15
	3Q	$0.00	$1.15	$1.40
	4Q	($0.21)	$1.40	$2.41
	FY	**($0.20)**	**$2.41**	**$2.72**
	P/E	NM	4.5x	4.0x

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Ardelyx announced tenapanor top-line results did not meet the primary endpoint in a Phase IIa study for the treatment of chronic kidney disease patients; we reiterate our Market Outperform while decreasing our price target to $24 from $32; eliminating CKD estimates from our model and increasing our discount rate on development in IBS-C and ESRD/hyperphosphatemia. Ardelyx announced that tenapanor did not met its primary efficacy endpoint of a statistically significant decrease of urinary albumin-creatinine ratio (UACR) from baseline to week 12 for tenapanor-treated patients compared to patients receiving placebo. The tenapanor-treated group demonstrated a 16% reduction in UACR versus 11% on placebo. Additionally, there was no significant effect observed on blood pressure, eGFR, nor a significant effect on sodium excretion. In line with results from the Phase IIb trial in hyperphosphatemia, there was a mean decrease in urinary phosphate levels with an increase of 53.1 mg/day in placebo versus a decrease of 118.6 mg/day in tenapanor. Finally, over two-thirds of patients experienced diarrhea on trial, an expected effect in light of the recent Phase IIb results in ESRD patients, where diarrhea was seen in up to 68% of patients in the high dose cohort. Importantly, the company has announced that its partner AstraZeneca (AZN, NC) has until June 29, 2015, to decide whether it will continue development of tenapanor in any indication. We believe that it is unlikely that AZN will continue development in CKD, but are convinced that a market opportunity in IBS-C and ESRD/hyperphosphatemia remains compelling considering the significant efficacy demonstrated in the Phase II trials. Removing CKD from our model and increasing our discount rate to reflect the uncertainty surrounding the AZN decision, we arrive at a $24 price target based on DCF and SOTP valuation methodologies.

If AZN opts out, getting tenapanor back is a very attractive scenario for ARDX. As a reminder, tenapanor demonstrated significant effects in IBS-C with a high responder rate in a placebo controlled trial, as compared to historical Linzess (linaclotide, IRWD, NC) response rates (Figures 2-4). Additionally, tenapanor demonstrated significant reductions in serum phosphorous in Phase IIb trials in dialysis patients with hyperphosphatemia (Figures 5 and 6). Discussions with management lead us to believe that incorporation of dose titration schemes into tenapanor studies would lead to a lower rate of discontinuations, more manageable gastrointestinal side effects, and an improved therapeutic index. In fact, the best tolerated dose in the CKD Phase IIa trial was higher when the patients were allowed to dose titrate, with fewer titrations. Given the likely incorporation of dose titration in a Phase III trial design, we believe tenapanor continues to present a compelling value proposition in the ESRD hyperphosphatemia market. In particular, diarrhea, constipation and other adverse effects are common in currently marketed phosphate binders.

Michael G. King, Jr.
mking@jmpsecurities.com
(212) 906-3520

From a competitive standpoint, tenapor's small pill burden is an important advantage. ARDX has indicated if the company were to regain rights to tenapanor, management would plan to continue development in IBS-C and ESRD/hyperphosphatemia. Given the greater economics in regaining control of a Phase III ready compound with compelling efficacy, we would view reacquiring the drug as a significant positive event.

Development pathway dependent on AZN decision. Currently, under the collaboration, AZN is responsible for tenapanor development in all indications, while ARDX receives royalties in the high single to mid-double digits, with milestones. If AZ were to continue development in IBS-C, ARDX would be entitled to a $10MM milestone. If AZ were to decide to advance into another indication such as ESRD/hyperphosphatemia, ARDX would be entitled to a $20MM milestone payment

Changes to our model. We are removing the CKD opportunity from our model which contributed $3.60 per share towards our sum-of-the-parts valuation. Additionally, we are increasing our discount rate from 30% to 35% for the ESRD/hyperphosphatemia indication to reflect the uncertainty surrounding the AZ decision, but also the risks involved in tenapanor's efficacy/tolerability profile in this patient population. Finally, we are also increasing our discount rate from 25% to 30% for the IBS-C indication to reflect the AZ-decision overhang. Changes to our model and valuation are presented in Figures 6-8.

While we are disappointed in today's news, we maintain our Market Outperform rating on shares of ARDX. At the close of business on May 5, 2015, ARDX's market cap was ~$200MM. It is well capitalized, in our view, with cash and equivalents of just over $100MM, along with a differentiated technology platform capable of churning out multiple clinical development candidates. The company also has a Phase III-ready asset that admittedly has had a difficult gestation period, but possesses a unique mechanism of action with a potentially differentiated profile and addresses large opportunities. The key challenge for the shares in the near term will be: anticipation of a decision by AZN as to which indication, if any, it wants to opt into; and, lack of positive data catalysts. For those small cap biotech investors who are willing to be patient, we believe buying on weakness will be well-rewarded.

FIGURE 1. Upcoming Catalysts

Timing	Program	Catalyst
29-Jun	Tenapanor	AZN Decision on continued development
2Q15	Tenapanor	Presentation of final results of Ph. IIB IBS-C data at DDW (Washington, DC)
2H15	Tenapanor	AZN go/no go decision
2H15	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers $50 million milestone payment)
4Q15	Tenapanor	Results of CKD data to be presented by AZ at ASN meeting (San Diego,CA)

Source: Company presentations

FIGURE 2. Tenapanor vs Linzess – Composite CSBM/Abdominal Pain

	Dual Composite Endpoint *versus* placebo				
	Week 2	**Week 3**	**Week 4**	**Week 6**	**Week 9**
Tenapanor 100 mg dose Phase IIA	30% *vs* 15%*	31% *vs* 20%	32% *vs* 19%	N/A	N/A
Tenapanor 50 mg BID dose Phase IIB (90 pts.)				50.0% vs. 23.6%**	
Linzess 290 mcg dose Phase III #1 (405 pts.)	*N/A*	*N/A*	*N/A*	33.6% vs 21%	12.1 % *vs.* 5.1%
Linzess 290 mcg dose Phase III #2 (401 pts.)	*N/A*	*N/A*	*N/A*	33.7% vs. 13.9%	12.7% *vs.* 3%

* p= < 0.05
**p=< 0.001

Source: Company reports

FIGURE 3. Relief of IBS-C symptoms

	Relief of IBS-C symptoms	
	Week 9	**Week 12**
Tenapanor 50 mg BID dose Phase IIB		63.1% vs 39.4%
Linzess 290 mcg dose Phase III #1	50.1% vs. 37.5%	
Linzess 290 mcg dose Phase III #2	48.9% vs. 34.5%	

Source: Company reports

FIGURE 4. Adverse Events

	Adverse Events	
	Tenapanor (50 mg BID)	**Linzess (290 mcg)**
Diarrhea	11.2% vs. 0%	20.0% vs 3%

Source: Company reporjts

FIGURE 5. Dose Response Results for Tenapanor Phase IIB in CKD Patients

	n	Change from Baseline	AE event rate due to diarrhea
1 mg BID	23	-0.47	26%
3 mg BID	21	-1.18	29%
10 mg BID	23	-1.7	48%
30 mg BID	24	-1.98	68%
3 mg QD	22	-0.56	18%
30 mg QD	21	-1.11	52%
Placebo	26	-0.54	12%
	Mean (treated)	-1.18	

Source: Company reports

FIGURE 6. Results of Phosphate Binder Phase IIB trials

	Tenapanor	Sevelamer	Ferric Citrate
# Patients	134	48	146
Dosage	1-30 mg	0.76-7.4 g	1-8 g
Mean Pi change mg/dL	(-1.2)	~(-1.1)	(-1.3)

Source: Company reports

FIGURE 7. SOTP Analysis

Sum of the Parts Valuation		
Market	**($ MM)**	**$/Share**
ESRD	**$ 28.36**	**$ 1.53**
IBS-C	**90.44**	**4.89**
Milestones	**233.41**	**12.63**
Cash	**107.29**	**5.81**
Value of Equity	**$ 460**	**$ 24.87**

Source: JMP Securities LLC

FIGURE 8. Discounted Cash Flow Analysis

Ardelyx (ARDX)												
Discount Cash Flow Model	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales and Royalty Revenue	-	-	-	-	2.8	24.2	76.1	126.3	162.1	185.6	202.1	211.5
License and milestone revenue	18.4	25.0	13.3	1.3	-	-	-	-	-	-	-	-
Milestone Revenue	-	45.0	75.0	65.0	117.5	130.0	225.0	106.8	70.0	-	-	-
Collaboration revenue	13.2	32.6	35.9	46.6	65.3	78.3	86.1	90.4	90.4	90.4	90.4	90.4
Total Revenues	31.6	102.6	124.2	112.9	185.6	232.5	387.2	323.5	322.6	276.1	292.6	301.9
R&D expenses	25.9	43.3	54.4	73.8	88.2	106.1	114.9	121.1	128.7	138.3	150.3	165.2
R&D as % of revenues	*81.9%*	*42.2%*	*43.8%*	*65.4%*	*47.5%*	*45.7%*	*29.7%*	*37.4%*	*39.9%*	*50.1%*	*51.4%*	*54.7%*
SG&A expenses	7.3	14.7	19.1	23.0	25.3	27.8	30.6	33.6	37.0	40.7	44.8	49.2
SG&A as % of sales	*23.0%*	*14.4%*	*15.4%*	*20.4%*	*13.6%*	*12.0%*	*7.9%*	*10.4%*	*11.5%*	*14.7%*	*15.3%*	*16.3%*
Operating Income (EBIT)	**(1.6)**	**44.6**	**50.6**	**16.1**	**72.1**	**98.6**	**241.7**	**168.8**	**156.8**	**97.1**	**97.6**	**87.5**
% Margin					*2572.6%*	*407.4%*	*317.7%*	*133.7%*	*96.7%*	*52.3%*	*48.3%*	*41.4%*
Taxes			-	-	-	-	12.1	16.9	31.4	34.0	34.1	30.6
Tax Rate	**0.0%**	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*5.0%*	*10.0%*	*20.0%*	*35.0%*	*35.0%*	*35.0%*
After-Tax Operating Income	**(1.6)**	**44.6**	**50.6**	**16.1**	**72.1**	**98.6**	**229.6**	**151.9**	**125.5**	**63.1**	**63.4**	**56.9**
% Margin			*40.8%*	*14.2%*	*38.9%*	*42.4%*	*59.3%*	*47.0%*	*38.9%*	*22.9%*	*21.7%*	*18.8%*
Discounting Year	-	-	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Discount Factor	1.00	1.00	1.32	1.73	2.28	3.00	3.96	5.21	6.86	9.03	11.88	15.64
PV	(1.6)	44.6	38.5	9.3	31.6	32.8	58.0	29.2	18.3	7.0	5.3	3.6
Terminal Value										**Terminal Value**		11.5

Residual Value of CF	**$**	**288**
+ Cash and Cash Equivalents	**$**	**107**
Value of Company	**$**	**395**
- LT Debt		
Value of Equity	**$**	**395**
Price/share=	**$**	**21.40**

Assumptions	
Blended Discount Rate	31.7%
Cash and Cash Equivalents On hand	$ 107.3
Terminal Growth Rate 2025	0%
Shares Outstanding (YE 2015 estimate)	18.5

Source: JMP Securities LLC, Company reports

FIGURE 9. ARDX Income Statement

Ardelyx Income Statement	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties															
Tenapanor - US					-	-	-	-	-	-	-	-	-	-	-
Tenapanor - WW Royalties					-	-	-	2.8	24.2	76.1	126.3	162.1	185.6	202.1	211.5
Total Sales and Royalties					-	-	-	2.8	24.2	76.1	126.3	162.1	185.6	202.1	211.5
Licensing revenue (amortization of upfront payments)	6.3	6.3	6.3	6.3	25.0	13.3	1.3	-	-	-	-	-	-	-	-
Milestones	-	-	20.0	25.0	45.0	75.0	65.0	117.5	130.0	225.0	106.8	70.0	-	-	-
Collaborative development revenue (reimbursment from AZN)	7.0	7.7	8.5	9.3	32.6	35.9	46.6	65.3	78.3	86.1	90.4	90.4	90.4	90.4	90.4
Total Revenues	13.3	14.0	34.7	40.6	102.6	124.2	112.9	185.6	232.5	387.2	323.5	322.6	276.1	292.6	301.9
% change															
Research and development	9.3	10.3	11.3	12.4	43.3	54.4	73.8	88.2	106.1	114.9	121.1	128.7	138.3	150.3	165.2
Selling, general and administrative	3.17	3.49	3.84	4.22	14.7	19.1	23.0	25.3	27.8	30.6	33.6	37.0	40.7	44.8	49.2
Total operating expenses	**12.5**	**13.7**	**15.1**	**16.6**	**58.0**	**73.6**	**96.8**	**113.4**	**133.9**	**145.5**	**154.7**	**165.7**	**179.0**	**195.0**	**214.5**
Operating Profit (Loss)	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.1	98.6	241.7	168.8	156.8	97.1	97.6	87.5
Margin(%)						*40.8%*	*14.2%*	*38.9%*	*42.4%*	*62.4%*	*52.2%*	*48.6%*	*35.2%*	*33.3%*	*29.0%*
Other income (expense)															
Total other income					-	-	-	-	-	-	-	-	-	-	-
Change in fair value of preferred stock warrant liability															
Pretax income	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.1	98.6	241.7	168.8	156.8	97.1	97.6	87.5
Provsion for income taxes					-	-	-	-	-	12.1	16.9	31.4	34.0	34.1	30.6
% Tax Rate										*5.0%*	*10.0%*	*20.0%*	*35.0%*	*35.0%*	*35.0%*
Net profit (loss) and comprehensive income	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.1	98.6	229.6	151.9	125.5	63.1	63.4	56.9
After Tax Margin(%)						*40.8%*	*14.2%*	*38.9%*	*42.4%*	*59.3%*	*47.0%*	*38.9%*	*22.9%*	*21.7%*	*18.8%*
Net profit (loss) attributable to common stockholders															
Basic															
Diluted															
Basic shares outstanding	17.1	17.1	17.1	17.1	17.1	17.2	17.2	17.3	17.4	17.4	17.5	17.6	17.7	17.7	17.8
Diluted shares outstanding	17.1	17.1	17.1	17.1	18.5	18.6	18.7	18.8	18.9	19.0	19.1	19.3	19.4	17.7	19.6
Basic GAAP EPS	**$ 0.05**	**$ 0.01**	**$ 1.15**	**$ 1.40**	$ 2.61	$ 2.95	$ 0.93	$ 4.17	$ 5.67	$ 13.16	$ 8.67	$ 7.13	$ 3.57	$ 3.57	$ 3.19
Diluted GAAP EPS	**$ 0.05**	**$ 0.01**	**$ 1.15**	**$ 1.40**	$ 2.41	$ 2.72	$ 0.86	$ 3.83	$ 5.21	$ 12.06	$ 7.93	$ 6.51	$ 3.26	$ 3.57	$ 2.90

Source: JMP Securities LLC, Company reports

Company Description

Ardelyx is a biopharmaceutical company focused on the development of therapies for the treatment of various cardiovascular, renal, and digestive disorders. By leveraging its unique platform combining non-systemic small molecule inhibitors and a proprietary cell culture system, Ardelyx has advanced tenapanor, an innovative candidate for the treatment of kidney disease and irritable bowel syndrome (IBS-C) in partnership with AstraZeneca. In addition to demonstrating preclinical and clinical efficacy in reducing the absorption of dietary sodium and phosphate, tenapanor has been shown to be safe and well-tolerated, having completed Phase I safety. Ardelyx expects data from its Phase IIB trial of tenapanor in IBS-C in 4Q2014, from its Phase IIB trial in hyperphosphatemia patients with end-stage renal disease (ESRD-Pi) in 1H2015, and its Phase IIA trial in patients with chronic kidney disease (CKD) in 2H15. Ardelyx also has research and development partnerships in place for its preclinical NaP2b inhibitor program with Sanofi.

Investment Risks

Potential risks to our price target include, but are not limited, to clinical and regulatory, partnering, reimbursement & commercial and competitive factors.

Clinical and regulatory. If tenapanor is not able to meet any of its primary outcomes or suffers from safety and tolerability issues, Ardelyx and AstraZeneca may choose to end development in any of its current indications. Additionally, if the FDA and EMEA do not approve tenapanor, Ardelyx's stock price would likely suffer.

Partnering. Ardelyx has partnered with AstraZeneca in the development of tenapanor and with Sanofi in the development of RDX002. AstraZeneca is responsible for the continued clinical and commercial development of tenapanor and may decide to end development for one or more indications. Additionally, Sanofi may not exercise its option to license RDX002 for clinical development. If it were necessary for Ardelyx to develop and market any of its programs due to the loss of or inability to retain a partner, it may be difficult to develop an internal commercial structure. Management has limited experience in commercial and marketing activities.

Reimbursement and commercial. The reimbursement landscape for dialysis drugs has shifted dramatically in recent years. In 2010, CMS introduced requirements for the fixed reimbursement "bundle" that have forced negative pricing pressure on injectables, such as erythropoietin-stimulating agents (e.g., EPO). The Protecting Access to Medicare Act of 2014 places ESRD oral therapeutics into the bundle beginning in 2024. The potential lack of separate reimbursement under Part D could make tenapanor unprofitable if these impacts on revenue are outpaced by rising costs of manufacture and marketing.

Competitive. There are a number of marketed and OTC therapies for several indications that Ardelyx is pursuing. There are several prescribed phosphate binders approved (Renagel/Renvela, PhosLo/Phoslyra, and Fosrenol), and in development (Zerenex, Alfaren, and Velphoro) for hyperphosphatemia. Sevlamer, the active ingredient in Renagel, goes off patent in 2014. Additionally, the IBS-C market has a number of OTC competitors (Miralax, Metamucil, Fibercon, Ex-lax) and several recently approved therapeutics (Linzess and Amitza). The CKD market is populated by a number of generic Angiotensin-converting enzyme (ACE) inhibitors and Angiotensin II receptor blockers (ARBs) that have similar minor efficacy in type 2 diabetic patients with moderately increased albuminuria.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.
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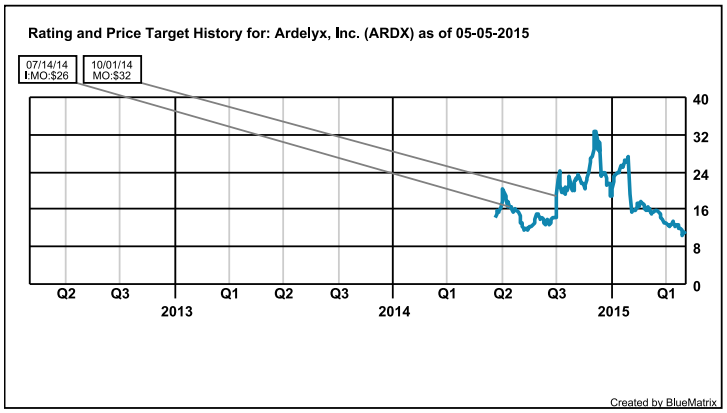
MARKET OUTPERFORM	Buy	280	*62.08%*	Buy	280	*62.08%*	94	*33.57%*
MARKET PERFORM	Hold	140	*31.04%*	Hold	140	*31.04%*	18	*12.86%*
MARKET UNDERPERFORM	Sell	9	*2.00%*	Sell	9	*2.00%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.66%*		21	*4.66%*	4	*19.05%*
TOTAL:		451	*100%*		451	*100%*	116	*25.72%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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Jeffrey H. Spurr
Director of Research
(415) 835-3903

RESEARCH PROFESSIONALS

FINANCIAL SERVICES

Alternative Asset Managers
Devin Ryan (212) 906-3578
Brian McKenna (212) 906-3545

Commercial & Specialty Finance
Christopher York (415) 835-8965

Consumer Finance
David M. Scharf (415) 835-8942
Douglas Greiner (212) 906-3525

Financial Processing & Outsourcing
David M. Scharf (415) 835-8942
Douglas Greiner (212) 906-3525

Insurance
Matthew J. Carletti (312) 768-1784
Christine Worley (312) 768-1786
Solomon Mindlin (212) 768-1788

Investment Banks & Brokers
Devin Ryan (212) 906-3578
Brian McKenna (212) 906-3545

Mortgage Operating Companies
REITs: Agency, Hybrid, & Commercial Mortgage
Steven C. DeLaney (404) 848-7773
Trevor Cranston, CFA (415) 869-4431
Charter Robinson (757) 613-8955
Benjamin Zucker (212) 906-3529

HEALTHCARE

Animal Health
J. T. Haresco, III, PhD (415) 869-4477

Biotechnology
Liisa A. Bayko (312) 768-1785
Masha Chapman (415) 835-8944
Bhumika Sharma, PhD (312) 768-1795
Jason N. Butler, PhD (212) 906-3505
Harry Jenq, PhD (212) 906-3509
Nazibur Rahman (212) 906-3519
Michael G. King, Jr. (212) 906-3520
Bryan Czyzewski, PhD (212) 906-3577
Eric Ekland (212) 906-3540
Naureen Quibria, PhD (212) 906-3514

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Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Brian Riley (415) 835-8908

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David Turkaly (212) 906-3563
John Gillings (212) 906-3564

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Aaron Hecht (415) 835-3963
Bharathwajan Iyengar (415) 835-3902

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Whitney Stevenson (212) 906-3538

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Mitch Germain (212) 906-3546
Peter Lunenburg (212) 906-3537

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Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Brian Riley (415) 835-8908

REITs: Office, Industrial, & Diversified
Mitch Germain (212) 906-3546
Peter Lunenburg (212) 906-3537

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Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Bharathwajan Iyengar (415) 835-3902

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Erik Suppiger (415) 835-3918
John Lucia (415) 835-3920

Internet & Digital Media
Ronald V. Josey III (212) 906-3528
Ignatius Njoku (415) 835-8960
Andrew Boone, CFA (415) 835-3957

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Patrick Walravens (415) 835-8943
Peter Lowry (415) 869-4418
Mathew Spencer (415) 835-8930
Greg McDowell (415) 835-3934
Rishi Jaluria (415) 835-3961

Wireless & Cloud Computing Technologies
Alex Gauna (415) 835-8998

ADDITIONAL CONTACTS

Thomas R. Wright
Director of Equities
(212) 906-3599

Thomas Healy
Head of Institutional Sales
(212) 906-3533

600 Montgomery Street, Suite 1100
San Francisco, CA 94111
www.jmpsecurities.com