

## Intercept Pharmaceuticals (ICPT)

**Increasing FV To \$56 From \$46 Due To Decreased Regulatory Risk In Our View, Inclusion Of RoW Revenues & Increased Pricing Estimates**

- **We have become more comfortable with FDA risk due to the EASL Supergroup abstract supporting the UK PBC Database results.** In March, data supporting use of alkaline phosphatase (ALP) as a surrogate clinical endpoint from the UK PBC database was published (Gastroenterology 2013 March; 144(3): 560-569). These results were also supported in a recently published abstract on interim results from about 2100 PBC "supergroup" patients to be presented as a poster (Abstract 941) on April 26<sup>th</sup> at The International Liver Congress (EASL April 24-28, 2013 Amsterdam). We believe these results are likely to convince the FDA to accept using ALP as a surrogate endpoint and an acceptable primary endpoint in PBC clinical trials. Due to our perception of reduced regulatory risk, we are comfortable with increasing our pricing and inclusion of rest-of-world revenue estimates in our net revenues used to calculate our fair value.
- **We see cash runway to mid-2015 covering eight transforming milestones.** Intercept ended 2012 with \$110.2MM in cash and equivalents, which the company projects can last into mid-2015. Key milestones include: (1) April 26: EASL poster presentation of the initial ~2,100 patient data set from the "supergroup" analysis supporting the use of the Phase 3 ALP/bilirubin endpoint as a surrogate for clinical outcomes; (2) Q2: Phase 2 top-line results for OCA treatment of bile acid diarrhea (OBADIAH trial, NCT01585025); (3) Q4: full "supergroup" data; (4) YE: full Phase 2a release for OCA treatment of portal hypertension (PESTO); (5) YE: initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint); (6) Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); (7) Q4:14: Initial results from FLINT Phase 2 trial testing OCA treatment of NASH as well as (8) NDA and MAA filings for OCA/PBC.
- **Reiterate OUTPERFORM rating but increasing fair value to \$56 from \$46 due to increased optimism and time value.** Our fair value is calculated by applying a 30% annual discount to our net peak WW revenues for each drug/indication and applying a 1-10x multiple depending on stage of development to reflect risk. Each combination is added in a sum-of-parts to calculate fair value for ICPT. We believe our previous \$46 fair value was based on conservative assumptions which we have increased due to our perceived reduction in regulatory risk.

FYE Dec	2011A	2012A			2013E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.0A	\$0.8A		--	\$0.4E		\$0.5E
Q2 Jun	0.0A	0.8A		--	0.4E		0.5E
Q3 Sep	0.0A	0.5A		--	0.4E		0.5E
Q4 Dec	0.0A	0.4A		--	0.4E		0.5E
Year*	<b>\$1.8A</b>	<b>\$2.4A</b>		--	<b>\$1.6E</b>		<b>\$2.0E</b>
Change	n/a	n/a			n/a		

	2011A	2012A			2013E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.00A	(\$1.03)A		--	(\$0.61)E	(\$0.65)E	(\$0.45)E
Q2 Jun	0.00A	(1.75)A		--	(0.63)E	(0.65)E	(0.46)E
Q3 Sep	0.00A	(1.86)A		--	(0.66)E	(0.65)E	(0.56)E
Q4 Dec	0.00A	(2.02)A		--	(0.69)E	(0.64)E	(0.60)E
Year*	<b>(\$4.73)A</b>	<b>(\$7.36)A</b>		--	<b>(\$2.60)E</b>	<b>(\$2.59)E</b>	<b>(\$2.08)E</b>
P/E	nm	nm			nm		
Change	n/a	n/a			n/a		

Consensus estimates are from Thomson First Call.

\* Numbers may not add up due to rounding.

April 15, 2013

Price  
**\$33.98**

Rating  
**OUTPERFORM**

Fair Value Estimate  
**\$56** (from \$46)

Liana Moussatos, Ph.D.  
(415) 263-6626  
liana.moussatos@wedbush.com

Richard Lau  
(415) 274-6851  
richard.lau@wedbush.com

### Company Information

Shares Outst (M)	18.2
Market Cap (M)	\$618.3
52-Wk Range	\$17.96 - \$42.67
Book Value/sh	\$3.62
Cash/sh	\$6.06
Enterprise Value (M)	\$508.2
LT Debt/Cap %	0.0%

### Company Description

Intercept Pharmaceuticals is an emerging biopharmaceutical company specializing in the development of bile acid therapies. The company's lead drug, Obeticholic Acid (OCA), is currently in Phase III development for the treatment of Primary Biliary Cirrhosis (PBC).



Source: Thomson Reuters

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## INVESTMENT THESIS

Intercept Pharmaceuticals is an emerging biopharmaceutical company developing small molecule drug treatments for significant unmet medical needs in orphan and other chronic liver diseases by leveraging its expertise and intellectual property in bile acid chemistry. We maintain an optimistic outlook for ICPT's attractive risk/reward profile as: 1) clinical success is likely; 2) regulatory risk is reasonable and continues to decline; and 3) commercial risk is below average.

Intercept's lead drug, obeticholic acid or OCA, has generated impressive efficacy data in two Phase 2 studies for the treatment of Primary Biliary Cirrhosis (PBC). In short, we believe OCA possesses one of the more clinically-derisked Phase 2 datasets among biotech drugs in development. PBC is a relatively well defined orphan market with a clear unmet medical need. Should OCA be approved, we believe the barriers to commercial adoption will be relatively low as patients are already identified and receiving treatment. Moreover, we see upside potential to our estimates of the eligible patient population as well as pricing, which may err on the conservative side. We see a high chance of success for Intercept's ongoing Phase 3 POISE study in PBC, with data expected in Q2:2014. Meanwhile, we see significant upside potential beyond PBC from follow-on indications such as portal hypertension, NASH and bile-acid diarrhea.

## NEAR-TERM MILESTONES

We estimate the following near and longer-term milestones for Intercept:

Expected Date	Event
April 26	Presentation of initial PBC biomarker "supergroup" analysis (Abs941 EASL 4/24-28 Amsterdam)
May 18-21	Topline results from Phase 2a OCA trial in bile acid diarrhea (OBADIAH) (DDW 5/18-21 Orlando)
H2:2013	Additional data presented on complete 4,000+ patient "supergroup" analysis of PBC biomarkers
H2:2013	Start of Phase 3 OCA confirmatory outcomes study in PBC
FY:2013	Additional data from OCA Phase 2a study in portal hypertension (PESTO)
<b>Q2:2014</b>	<b>Topline data from pivotal Phase 3 POISE study of OCA in PBC</b>
Q4:2014	Topline data from Phase 2 FLINT study of OCA in NASH
Mid:2015	Potential US Approval of OCA for the treatment of PBC

## VALUATION AND RISKS

Our fair value of \$56 is calculated using a sum-of-parts analysis, applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA for the treatment of PBC, portal hypertension and NASH. Given the evolving outlook regarding key variables such as pricing, market size and clinical profile of OCA in the different indications, we see room for additional upside beyond our fair value.

Risks to the attainment of our fair value include: Intercept's products obtain disappointing clinical trial results and/or fail to gain regulatory approval; Intercept is unable to pursue accelerated approval for OCA in the US or faces lengthy regulatory delays; Intercept or a partner fails to effectively commercialize its drug products due to unenthusiastic physician response or superior clinical results are obtained by a third-party competitor; unexpected safety problems emerge with Intercept's drug products; Intercept is unable to raise additional capital, if necessary, at terms favorable to shareholders.

We use multiples to account for clinical and regulatory risk at various stages of development.				Today: 4/12/13 Stock MktCap (\$000) Upside								
				Wedbush Fair Value for ICPT \$55.50 \$1,009,980 63%								
1: In preclinical testing		6: Phase III testing		Full Pipeline Value: \$56.04 \$1,019,722								
2: Passed preclinical		7: Phase III data (positive)		Net Cash: \$6.06 \$110,194								
3: IND filed		8: Regulatory review		ICPT Total Value: \$62.09 \$1,129,916								
4: Phase I data (positive)		9: Approved		Current ICPT Stock: \$33.98 \$618,344								
5: Phase II data (positive)		10: Launched		ICPT Diluted Shares Outstanding (000s): 18,197								
Intercept Pipeline Valuation												
Product		Indication	Eligible # Annual WW Treatable 2nd Line Patients Est	Pricing (WW Wtd Avg \$USD / Patient / Year)	WW Wtd Avg Peak Penetration Est	Gross WW Peak Sales Est (\$000)	ICPT Net Peak Revs Est WW + Upfront & Miles (\$000)	1st Estimated Launch	Multiple	Annual Discount Rate	Wedbush MktCap Fair Value (\$000)	Wedbush Stock Fair Value
FXR Agonist	OCA (INT-747)	PBC	18,040	\$67,400	40%	\$517,440	\$586,544	4/1/2015	6	30%	\$734,896	\$40.38
FXR Agonist	OCA (INT-747)	Portal Hypertension	432,000	\$12,008	11%	\$684,000	\$422,100	7/1/2017	5	30%	\$187,763	\$10.32
FXR Agonist	OCA (INT-747)	NASH	10,440,000	\$2,047	2%	\$360,000	\$318,995	7/1/2018	4	30%	\$87,322	\$4.80
FXR Agonist	OCA (INT-747)	Bile Acid Diarrhea	3,960,000	\$1,915	12%	\$697,500	\$326,500	7/1/2017	3	30%	\$87,142	\$4.79
TGR5 Agonist	INT-777	Type II Diabetes	34,400,000	\$3,844	1%	\$2,437,000	\$181,850	6/1/2019	1	30%	\$9,782	\$0.54
FXR/TGR5 Agonist	INT-767	Fibrosis	13,200,000	\$1,915	1%	\$421,953	\$181,098	6/1/2019	1	30%	\$9,741	\$0.54

Source: Company reports, Wedbush Securities research

# Intercept Pharmaceuticals (NASDAQ: ICPT)

## Historical and Projected Income Statement

(In thousands except per share data)

(Fiscal Year Ends on December 31)

Wedbush PacGrow LifeSciences

Liana Moussatos, Ph.D.

Richard Lau

	2012A	2013E					2014E	2015E	2016E	2017E
	FY:12A	Q1	Q2	Q3	Q4	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
Gross Product Sales:										
OCA (INT-747)								30,314	105,097	221,472
PBC								-	-	6,696
Portal Hypertension								-	-	14,062
Bile Acid Diarrhea								-	-	-
Revenues/Royalties on Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 30,314	\$ 104,236	\$ 224,671
OCA (INT-747)								30,314	104,236	214,037
PBC	-	-	-	-	-	-	-	-	-	6,696
Portal Hypertension	-	-	-	-	-	-	-	-	-	3,937
Bile Acid Diarrhea	-	-	-	-	-	-	-	-	-	-
Collaboration Revenue	\$ 2,446	\$ 400	\$ 400	\$ 400	\$ 400	\$ 1,600	\$ 1,600	\$ 1,600	\$ 1,600	\$ 1,600
<b>Total Revenues</b>	<b>\$ 2,446</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 1,600</b>	<b>\$ 1,600</b>	<b>\$ 31,914</b>	<b>\$ 105,836</b>	<b>\$ 226,271</b>
<b>Operating Expenses</b>										
Cost of Goods								1,819	6,240	13,125
Research and Development	16,183	4,978	5,277	5,647	6,098	22,001	28,996	34,292	40,116	46,930
Sales, General and Administrative	5,177	2,292	2,407	2,527	2,653	9,879	12,312	28,049	43,372	50,739
Other	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>21,360</b>	<b>7,271</b>	<b>7,684</b>	<b>8,174</b>	<b>8,752</b>	<b>31,880</b>	<b>41,308</b>	<b>64,159</b>	<b>89,728</b>	<b>110,794</b>
Operating Income (Loss)	(18,914)	(6,871)	(7,284)	(7,774)	(8,352)	(30,280)	(39,708)	(32,245)	16,108	115,476
Interest and dividend income	92	18	27	25	23	93	68	26	12	12
Interest (expense)	(4)	-	-	-	-	-	-	-	-	-
Revaluation of warrants	(24,625)	(2,500)	(2,500)	(2,500)	(2,500)	(10,000)	-	-	-	-
Other income (expense)	(192)	-	-	-	-	-	-	-	-	-
<b>Income Before Income Taxes</b>	<b>(43,644)</b>	<b>(9,352)</b>	<b>(9,757)</b>	<b>(10,249)</b>	<b>(10,829)</b>	<b>(40,187)</b>	<b>(39,640)</b>	<b>(32,219)</b>	<b>16,120</b>	<b>115,488</b>
Other comprehensive income (loss)	(2,630)	-	-	-	-	-	-	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	2,819	25,280
<b>Net Income (Loss)</b>	<b>\$ (46,274)</b>	<b>\$ (9,352)</b>	<b>\$ (9,757)</b>	<b>\$ (10,249)</b>	<b>\$ (10,829)</b>	<b>\$ (40,187)</b>	<b>\$ (39,640)</b>	<b>\$ (32,219)</b>	<b>\$ 13,301</b>	<b>\$ 90,209</b>
EPS ( Basic & Diluted; Pro forma)	(7.36)	(0.61)	(0.63)	(0.66)	(0.69)	(2.60)	(2.50)	(1.94)	0.68	4.50
Shares Outstanding (Basic)	6,283	15,323	15,423	15,523	15,623	15,473	15,873	16,648	17,648	18,648
Fully Diluted Shares Outstanding		18,297	18,397	18,497	18,597	18,447	18,847	19,247	19,647	20,047
<b>Net Cash</b>	<b>\$110,272</b>	<b>\$103,448</b>	<b>\$95,998</b>	<b>\$88,105</b>	<b>\$79,689</b>	<b>\$79,689</b>	<b>\$36,641</b>	<b>\$2,610</b>	<b>\$14,844</b>	<b>\$104,179</b>
<b>Change in Cash (Burn)</b>	<b>\$92,363</b>					<b>(\$30,583)</b>	<b>(\$43,048)</b>	<b>(\$34,031)</b>	<b>\$12,235</b>	<b>\$89,334</b>

Margins:	FY:12A	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
COGs %	N/A	N/A	N/A	6%	6%	6%
Gross Margin	N/A	N/A	N/A	94%	94%	94%
Operating Margin	-773%	-1718%	-1821%	-101%	15%	51%
Net Income	-1892%	-2338%	-2439%	-101%	13%	40%

Growth Rates (y/y):	FY:12A	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
Revenue	135%	53%	53%	76%	99%	65%
Operating Income	N/M	N/M	N/M	N/M	N/M	100%
Income Before Taxes	N/M	N/M	N/M	N/M	N/M	1995%
Net Income	N/M	N/M	N/M	N/M	N/M	332%

Source: Company reports, Wedbush Securities research.

## Analyst Biography

*Ms. Moussatos is a Managing Director, Equity Research responsible for the coverage of stocks in the Emerging Pharmaceuticals sector. Liana joined Wedbush from Pacific Growth Equities where she was a Senior Research Analyst. Prior to that she came from UBS Global Asset Management where she was Director and Portfolio Manager of the UBS Global Biotech Funds for five years. Previously Liana was with Bristol-Meyers Squibb where she was a manager in University and Government Licensing External Science and Technology and she also worked with Sloan-Kettering Cancer Institute in the Office of Industrial Affairs and the National Cancer Institute in the Office of Technology Development.*

*Liana received a B.S. in Entomology and a M.S. in Zoology and Biochemistry from Clemson University and a Ph.D. in Plant Pathology from the University of California Davis and completed a postdoctoral research fellowship in Cellular and Molecular Physiology at the Yale School of Medicine.*

*Liana's Edge: Liana's industry and buy-side experience provide depth in her understanding of what investors need to know along with her 13 years experience in following healthcare stocks. Her pipeline valuation includes all drug candidates / disease indications in active development and provides investors with a stock value for each program.*

## Analyst Certification

I, Liana Moussatos, Ph.D., Richard Lau, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).\*

Rating Distribution (as of March 31, 2013)	Investment Banking Relationships (as of March 31, 2013)
Outperform: 51%	Outperform: 18%
Neutral: 44%	Neutral: 2%
Underperform: 5%	Underperform: 0%

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Company	Disclosure
Intercept Pharmaceuticals	1,3,4,5,7

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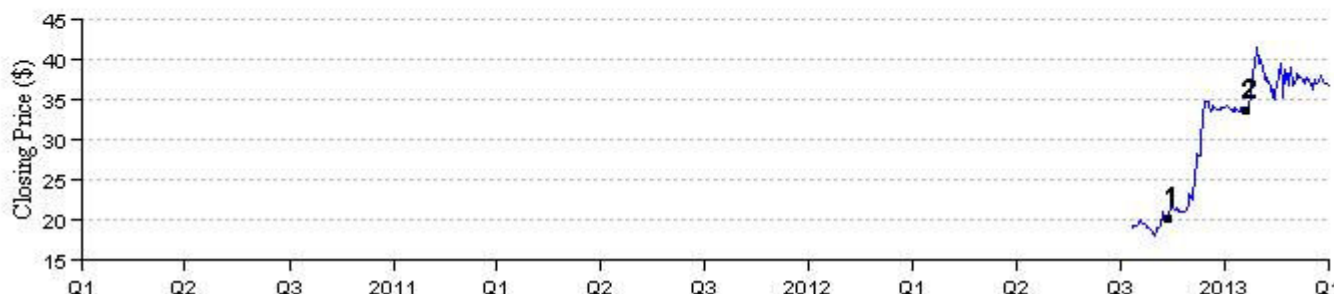
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### ICPT

1) 11/08/12	2) 01/16/13
OUTPERFORM \$25	OUTPERFORM \$48



\* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009. Please access the attached hyperlink for WS' Coverage Universe: <http://www.wedbush.com/services/cmg/equities-division/research/equity-research>. Applicable disclosure information is also available upon request by contacting Ellen Kang in the Research Department at (213) 688-4529, by email to [ellen.kang@wedbush.com](mailto:ellen.kang@wedbush.com), or the Business Conduct Department at (213) 688-8090. You may also submit a written request to the following: Business Conduct Department, 1000 Wilshire Blvd., Los Angeles, CA 90017.

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**RESEARCH DEPT. \* (213) 688-4505 \* [www.wedbush.com](http://www.wedbush.com)**  
**EQUITY TRADING** Los Angeles (213) 688-4470 / (800) 421-0178 \* **EQUITY SALES** Los Angeles (800) 444-8076  
**CORPORATE HEADQUARTERS** (213) 688-8000

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## EQUITY RESEARCH DEPARTMENT

(213) 688-4529

### DIRECTOR OF RESEARCH

Mark D. Benson (213) 688-4435

### MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

#### RETAIL AND CONSUMER

##### Consumer Products

Rommel T. Dionisio (212) 938-9934  
Kurt M. Frederick, CFA CPA (415) 274-6822

##### Footwear, Apparel and Accessories

Corinna Freedman (212) 668-9876

##### Healthy Lifestyles

Kurt M. Frederick, CFA CPA (415) 274-6822

##### Restaurants

Nick Setyan (213) 688-4519  
Colin Radke (213) 688-6624

##### Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537  
John Garrett, CFA (213) 688-4523

##### Specialty Retail: Softlines

Betty Chen (415) 273-7328  
Alex Pham (415) 273-7315

#### RETAIL/CONSUMER MARKET RESEARCH

Gabriella Santaniello (213) 688-4557

#### INDUSTRIAL GROWTH TECHNOLOGY

##### Clean Technology

Craig Irwin (212) 938-9926  
Min Xu (212) 938-9925

##### Environmental Services

Al Kaschalk (213) 688-4539  
Scott Buck (213) 688-4303

##### Industrial Biotechnology

Liana Moussatos, Ph.D. (415) 263-6626  
Christopher N. Marai, Ph.D. (415) 274-6861

##### Water and Renewable Energy Solutions

David Rose, CFA (213) 688-4319

#### TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

##### Communications Equipment

Rohit Chopra (212) 668-9871  
Sanjit Singh (212) 938-9922  
Ryan Flanagan (212) 938-9942

##### Computer Services: Financial Technology

Gil B. Luria (213) 688-4501  
Aaron Turner (213) 688-4429

##### Enterprise Software

Steve Koenig (415) 274-6801

##### Entertainment: Retail

Michael Pachter (213) 688-4474  
Nick McKay (213) 688-4343  
Alicia Reese (212) 938-9927

##### Entertainment: Software

Michael Pachter (213) 688-4474  
Nick McKay (213) 688-4343

##### Internet and E-Commerce

Michael Pachter (213) 688-4474  
Nick McKay (213) 688-4343  
Alicia Reese (212) 938-9927

##### Media

James Dix, CFA (213) 688-4315  
Alicia Reese (212) 938-9927

##### Movies and Entertainment

Michael Pachter (213) 688-4474  
Nick McKay (213) 688-4343  
Alicia Reese (212) 938-9927

##### Semiconductors

Betsy Van Hees (415) 274-6869  
Ryan Yue, CFA (415) 263-6669

#### LIFE SCIENCES

##### Biotechnology/Biopharmaceuticals/BioDefense

Gregory R. Wade, Ph.D. (415) 274-6863  
David M. Nierengarten, Ph.D. (415) 274-6862  
Christopher N. Marai, Ph.D. (415) 274-6861

##### Emerging Pharmaceuticals

Liana Moussatos, Ph.D. (415) 263-6626  
Richard Lau (415) 274-6851  
Christopher N. Marai, Ph.D. (415) 274-6861

##### Healthcare Services - Managed Care

Sarah James (213) 688-4503  
Daniel Patt (212) 938-9937

##### Medical Diagnostics and Life Sciences Tools

Zarak Khurshid (415) 274-6823

#### EQUITY SALES

Los Angeles (213) 688-4470 / (800) 444-8076  
San Francisco (415) 274-6800  
New York (212) 938-9931  
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#### EQUITY TRADING

Los Angeles (213) 688-4470 / (800) 421-0178  
San Francisco (415) 274-6811  
New York (212) 344-2382  
Boston (617) 832-3700

#### CORPORATE HEADQUARTERS

1000 Wilshire Blvd., Los Angeles, CA 90017-2465  
Tel: (213) 688-8000 [www.wedbush.com](http://www.wedbush.com)