



## **Overview of Market Research Services**

January 2012

## **BioTrak Fact Sheet**

- Founded in 1999 to provide commercial support and new product planning consulting services to the pharmaceutical and medical device industry
- Team of 10 including researchers, pharmacists, regulatory, biostatistics experts, and support staff based in Carlsbad, California
- Leadership from the pharmaceutical industry
- Conducted over 300 total research studies and over 100 web-based questionnaire survey studies with patients, health care providers, and pharmacists
- Innovator in the use of probabilistic modeling technique for forecast and market share predictions
- Recent launch its own online ailment panel, GoHealthPanel.com, to support subject recruitment and research fielding.



## About BioTrak

## **Core Consulting Services:**

- Market Research :
  - » Quantitative Research:
    - Awareness, Trial and Usage (ATU/AUU) Rx tracking studies
    - KAB (Knowledge, Attitude, and Behavior) surveys
    - Forecast prediction models using probabilistic modeling techniques (e.g., Monte Carlo analysis)
    - Conjoint analysis and simulator models
    - Product concept testing
    - Readability and comprehension testing for consumer and healthcare professional medical information
  - » Survey design, web programming, and hosting
  - » Subject recruitment
- REMS assessments



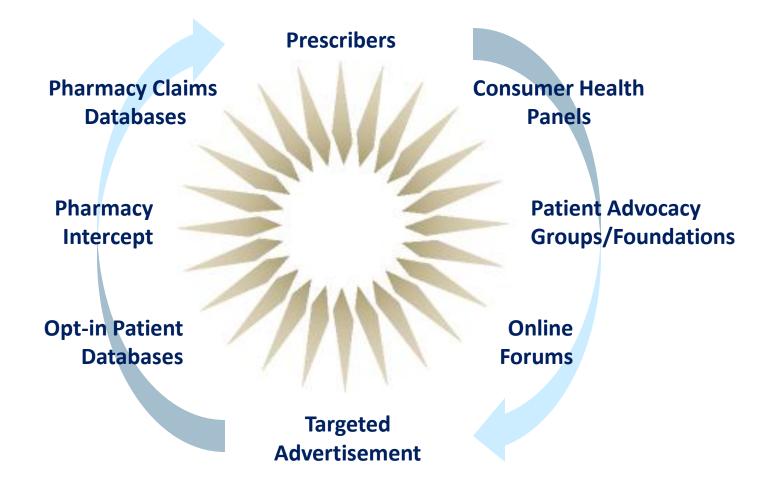
## BioTrak Operates a Secure Survey Portal with Real-Time Data Reporting





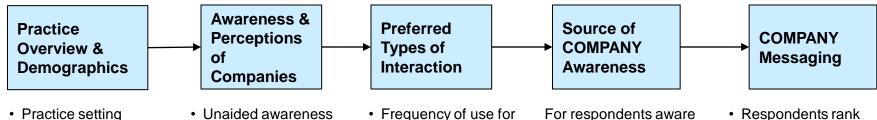
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## Multimodal Recruitment Capabilities

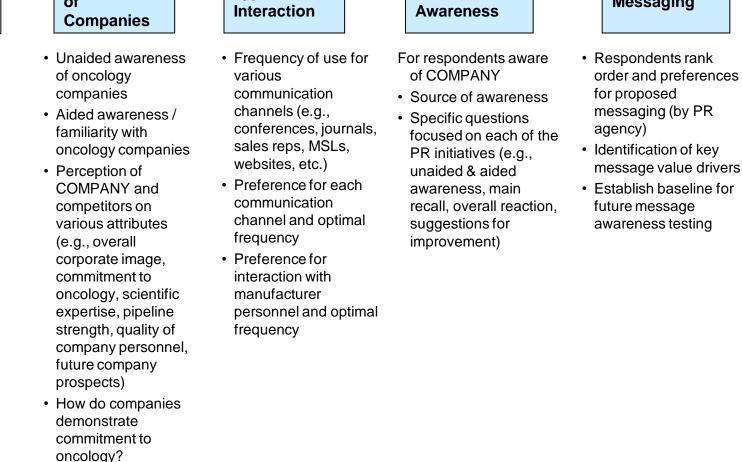




## Methodology: ATU Studies



 Number of target patients seen in a typical month by tumor type





The forecast model is a six-part model construct designed as a <u>risk-adjusted probabilistic potential</u> <u>market forecast based upon Monte Carlo simulation.</u>



### Patient-Based Model

- Useful for assessing new markets
- Includes value of unserved market
- "Ground up" approach



#### Intended Use Discount

- Composite discount factor
- Yields expected patient access



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#### Potential Available Market

- Available total expected market size
- A prediction of peak sales potential



#### **Utilization Metrics**

- Duration of Tx, DACON
- -1<sup>st</sup> line vs. 2<sup>nd</sup> line, episodes/yr etc
- Incorporates distribution fits for sample



#### Analog Curve

- Expected market penetration rate
- Modeled for "analogous" drug experiences



#### **Probabilistic Forecast Model**

- Expected product gross revenues
- Monte Carlo simulation output gives lower and upper 5% boundaries and mean

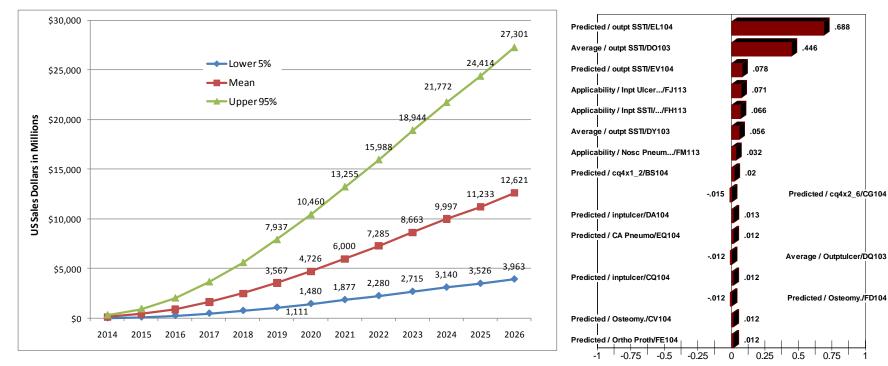


## Methodology: Prediction Forecast Models

The forecast model is designed as a <u>risk-adjusted probabilistic potential market forecast based</u> <u>upon Monte Carlo Simulation.</u>

Example Output:

13-Year Forecast Prediction



#### Tornado graph for sensitivity analysis

Std b Coefficients



## Methodology: Decision Tool Optimizer

## BioTrak's forecast methodology flows seamlessly into its Decision Tool Optimizer for convenient licensing and deal structuring simulations that maximize for ENPV outputs.

#### Risk-Adjusted Drug ENPV Calculator and Decision Tool Optimizer - Optimizer 1.0 - copyright BioTrak Consulting Group November 2005

Prediction of Potential Market		Phase I	Phase II	Phase III	NDA	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Potential Available Treatment Days	20,000,000	from patient-based model				27,717,174	30,073,134	32,629,350	35,402,845	38,412,087	41,677,114	45,219,669	49,063,341	53,233,725	57,758,59
Daily Medication Cost	\$13.50					\$16.10	\$16.82	\$17.58	\$18.37	\$19.20	\$20.06	\$20.97	\$21.91	\$22.89	\$23.92
Potential Expected Market (000s)						\$446,219	\$505,934	\$573,641	\$650,408	\$737,449	\$836,138	\$948,034	\$1,074,905	\$1,218,754	\$1,381,8
Market Liptake Apalog	Analog 2: maximum at 5	vears				12.1%	30.0%	54.6%	72.5%	78.0%	75.0%	67.0%	50.0%	30.0%	15.0%
Drug Forecast (000s)		,				\$53,906	\$151,718	\$313,406	\$471,816	\$575,210	\$627,104	\$635,183	\$537,452	\$365,626	\$207,27
Didg Foredast (0003)						\$00,000	¢101,110	<i><b>4010</b>,100</i>	¢111,010	\$010,210	<i>4021,101</i>	\$000,100	\$001,102	\$000,020	φ201,21
Competitive Risk Discount	70.0%					70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%
Risk-Adjusted Forecast (000s)						\$37,735	\$106,203	\$219,384	\$330,271	\$402,647	\$438,973	\$444,628	\$376,217	\$255,938	\$145,09
COGS	5.0%					5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
*Pre- & Post-launch Expense (000s)	0.070			\$5,000	\$10.000	\$15,000	\$5,000	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070
Product SG&A				\$0,000	\$10,000	28.0%	28.0%	25.0%	24.0%	24.0%	24.0%	24.0%	24.0%	24.0%	24.0%
Product Profit		\$0	\$0	(\$5,000)	(\$10,000)	\$10,282	\$66,156	\$153,569	\$234,493	\$285,879	\$311,670	\$315,686	\$267,114	\$181,716	\$103,01
Development and Prelaunch		Phase I	Phase II	Phase III	NDA	-									
Development to be Completed		V	V	Flidse III	NDA										
Development to be Completed Duration of Phase		12	12	12	12	-									
Phase Probability of Success	Miscellaneous	56%	36%	53%	67%										
Cumulative Probability of Success	Wiscellarieous	56%	20%	10%	7%										
R&D Expense (000s)		\$5,000	\$15,000	\$30,000	\$1,000										
Originator		\$0,000	\$10,000	400,000	\$1,000								1		
- Upfront Payment (000s)		\$5,000													
Milestone Payments (000s)			\$1,000	\$1,000	\$1,000										
Reimbursed R&D (000s)		\$1,000	\$1,000	\$1,000	\$1,000										
Royalty on Net Sales (000s)	14.0%					\$5,283	\$14,868	\$30,714	\$46,238	\$56,371	\$61,456	\$62,248	\$52,670	\$35,831	\$20,31
Money Factor	23.5%	1.24	1.53	1.88	2.33	2.87	3.55	4.38	5.41	6.68	8.25	10.19	12.59	15.55	19.20
Expected DCFs (000s)		(\$175)	(\$17,168)	(\$35,523)	\$433	\$1,839	\$4,190	\$7,009	\$8,544	\$8,434	\$7,446	\$6,106	\$4,184	\$2,305	\$1,058
Risk Adjusted ENPV (000s)	(\$1,318)	-\$175	-\$17,343	-\$52,866	-\$52,433	-\$50,594	-\$46,403	-\$39,394	-\$30,850	-\$22,416	-\$14,970	-\$8,864	-\$4,680	-\$2,376	-\$1,318
Partner															
R&D Contribution		\$5,000	\$5,000	\$5,000	\$5,000										
Payments to Originator		\$6,000	\$2,000	\$2,000	\$2,000	\$5,283	\$14,868	\$30,714	\$46,238	\$56,371	\$61,456	\$62,248	\$52,670	\$35,831	\$20,31
Total Contribution		\$11,000	\$7,000	\$7,000	\$7,000	\$5,283	\$14,868	\$30,714	\$46,238	\$56,371	\$61,456	\$62,248	\$52,670	\$35,831	\$20,31
	4 00/	1.24	1.53	1.88	2.33	2.87	3.55	4.38	5.41	6.68	8.25	10.19	12.59	15.55	19.20
Money Factor	1.0%	1.24													
	1.0%	(\$13,585)	(\$10,677)	(\$13,186)	(\$16,284)	\$5,418	\$22,836	\$42,055	\$51,875	\$51,208	\$45,205	\$37,075	\$25,401	\$13,992	\$6,423

for assistance or to procure primary research data, contact BioTrak www.biotrak.com 760-448-4820



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## BioTrak Research and Support Team



### Research Director

Larry Risen, MBA

- 23 years medical industry commercial experience
- Project leader/director on over 300 consulting assignments involving new product planning, forecasting and commercialization strategy for new therapeutics, devices, and diagnostics
- Key researcher on numerous opportunity assessments
- Expert at forecast model development
- Over 3,000 physicians interviewed
- Managed 20 new product launches 3 Rx, 17 Dx
- Built 2 specialty pharma commercial programs from ground up
- Currently BioTrak President and Senior Consultant

#### **Consulting Team**

#### <u>Walter R. Paczkowski, Ph.D</u> BioTrak Biostatistician

· Advanced analytics and statistics

#### <u>Gerard Smits, Ph.D</u> BioTrak Biostatistician

· Advanced analytics and statistics

#### AnnKatrin Petersen, M.D., M.S. Chief Medical Officer

• Clinical research and pharmacoeconomics expertise

#### <u>Carl Kremer, Ph.D</u> Medical Affairs and Research

- Pharmacy expertise
- Dx/Tx Pathways and algorithms

#### Administrative Support Staff



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## Contact

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