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## BIOPARTNERING REPORT 2009: STRATEGIES AND PARADIGMS OF THE DEAL

Executive Summary

By Michael Harris, BioWorld Executive Editor and Amanda Lyle, BioWorld Managing Editor

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#### Introduction and Analysis

#### Trends

Depressing First Half of 2008 in Worldwide Public Markets Drug/Device Combos Could Salvage Dropped Compounds A Match Made in Heaven; R&D Productivity Via Partnering Drug and Medical Device Deals: A Different Type of Partnership As Big Pharma Model Falters, Biotech Rides to the Rescue Deals to M&As: The Culture of False-Flagging, Shape-Shifting

#### Notable Deals

#### Autoimmune and Inflammation Deals

Immunomedics Inks Potential \$620M Deal with Nycomed ARYx Seeking New Partner for GI Program after P&G Bails Out UCB Licenses Keppra, Cimzia Rights in Japan Alizyme, Norgine Team Up in \$67M Marketing Deal Bionomics Signs Merck Serono in MS, Autoimmune Partnership TransPharma Gets \$35M in Osteo Deal with Lilly OLT Sells Acne Gel Product Aczone for \$150M to Allergan Start-up TFT Adds NF-Kappa B Decoy Program from Anesiva Early Stage Antibody Nets EUSA \$44M from GSK Scil, Pfizer Enter \$250M Deal for Preclinical Osteo Drug Catalyst Partners with Centocor for Engineered Protease Drugs Galapagos Inks \$395M Deal with Lilly for Osteo Drugs Alba Inks Ex-U.S./Japan Deal with Shire for Celiac Drug Excaliard Snags \$15.5M and Isis Fibrosis Drugs Galapagos and Janssen in RA Partnership Axcan, Cellerix Deal for Adult Stem Cell Therapy Radius Grants Novartis Option to BA058 in Potential \$500M Deal Microbia, Forest Collaborate: Up to \$330M for IBS Candidate LigoCyte, Biogen Partner for Work on Inflammatory Diseases Merck, KineMed Collaborate on Atherosclerosis in RCT Deal Micromet, Nycomed Enter GM-CSF Deal

#### **Cancer Deals**

Seattle Genetics Nets \$4M in Deal with Daiichi Sankyo Exelixis, GSK Wrap Up Six-Year Discovery, Development Deal ThromboGenics, BioInvent in \$775M Roche Oncology Deal Astex Strikes \$500M Deal for its Fibroblast Receptor ImaRx Shares Spike on Sale of Urokinase to Microbix

CuraGen Sells Cancer Drug to TopoTarget for \$45M Avant, Pfizer Sign \$50M Deal for GBM Cancer Vaccine Amgen Gaining Rights to CCR4 Antibody in \$520M Kyowa Deal Dyax Signs Sanofi to Antibody Deal Potentially Worth \$500M Amgen Unloads 13 Molecules in \$1B-plus Deal with Takeda Alfacell Deals U.S. Rights for Onconase to Strativa ImmunoGen Entering TAP Cancer Deal with Centocor Aegera Adds Millions to Coffers in Year-End Deal Nektar and Baxter Enter Second Hemophilia Agreement Idera Signs \$421M Deal for TLR9 Cancer Agonists Antibody Deal with GSK Netting OncoMed \$1.4B Merck Serono Takes Japanese Option to R763 from Rigel Infinity Regains Hedgehog Pathway Inhibitor Program Synta, GSK Partner for Melanoma Drug in Deal Worth up to \$1B OSI, AVEO Targeting EMT in Cancer Research Collaboration AVEO Growing Antibody Pipeline Celgene Paying Array \$40M Up Front for Drug Discovery Pharmion, MethylGene Team for \$100M Cancer Partnership Cell Therapeutics Buys Zevalin in Anticancer Deal Worth \$30M Ariad and Merck Enter Deal on mTOR Inhibitor Genentech, Abbott Partner to Develop Oncology Drugs Novacea, Schering-Plough Enter Potential \$440M Deal

#### Cardiovascular and Anemia Deals

Addrenex Signs Second Sciele Deal KAI, BMS Join Forces in \$227M Heart Drug Deal Wyeth Cancels Hedgehog Collaboration with Curis Amira Inks \$425M FLAP Inhibitor Deal with GSK PDL Divestiture Continues in \$170M Deal with EKR Inspiration Teams with Celtic in \$35M Hemophilia Deal Isis Pockets \$325M Up Front in \$1.9B Deal with Genzyme ThromboGenics: Another Deal for Staphylokinase Heart Drug Keryx, Japan Tobacco Deal: Possible \$100M for Zerenex BioLineRx Gets BL-4040 Rights; Delves Into Acute Kidney Injury Isis, BMS Enter Deal on Early Stage Cholesterol Drug

#### Central Nervous System Deals

Actelion, GSK Ink \$3.2B Deal with Almorexant as Centerpiece Proximagen Stands to Get \$232M in Deal for Parkinson's Drug Myriad Gets \$100M Upfront in European Deal for Flurizan Spectrum Sale of Profit Shares of Migraine Drug Nets \$20M Astellas, CoMentis in \$760M Deal for Alzheimer's Treatment \$135M Deal Saves Shire Two Years Toward CNS Drug Vernalis Takes \$29M for Now, Giving Up Migraine Revenues Antisense Licenses MS Drug to Teva for \$2M Up Front Rights to Schizophrenia Drug Worth up to \$702M for Addex Sepracor in \$175M Deal with Bial for Epilepsy Drug BioMS Signs \$497M Deal with Lilly for SPMS Drug Addex Inks \$170M Merck Deal for CNS Drug Development Biogen, Neurimmune Entering Alzheimer's Deal: Up to \$360M

#### Diabetes and Obesity Deals

Depomed Gets \$12M Up Front in Diabetes Deal with Santarus Diabetes Deal Brings Emisphere Up to \$87M from Novo Nordisk Transition Could Get \$130M in Diabetes Deal with Lilly Alkermes Left at the Altar as Lilly Kills AIR Program Teva Amends Andromeda Deal for Phase III Diabetes Drug Smoke Clears; Pfizer Paying Nektar \$135M in Exubera Deal Tolerx, GSK Partner on \$760M Diabetes/Psoriasis Product Hard-Pressed Pfizer Dropping Exubera; Nektar Shares Slump MacroGenics, Lilly Ink \$1B Deal for Diabetes Drug Teplizumab Vitae, BI Combine Metabolic Programs in \$336M Deal XenoPort Partners Early Stage Candidate in \$147M Deal MedImmune, Crucell in Antibody Deal of up to \$40M Pharmacopeia Adds SARM Program in BMS Deal Gene Logic Sheds Genomics Assets Isis Gets \$45M Up Front in Deal with Ortho on Diabetes Drugs

#### HCV and HIV/AIDS Deals

Symphogen, Genentech Sign Antibodies Deal Worth \$330M Vertex Sells Royalty Rights to HIV Inhibitors for \$160 Million Medivir, Tibotec Expand HCV Work in Potential \$430M Deal Presidio Gains Early Hepatitis C Program from XTL in \$108M Deal Tacere Signs Oncolys as Asian Partner in \$60M HCV Agreement ProMetic Partners with Kedrion on Plasma-Derived Proteins Tacere's shRNA Drug for HCV Subject of \$145M Pfizer Deal Crucell Signs Sanofi Pasteur in \$113M Rabies Antibodies Deal Santaris Gets \$700M from GSK in Antiviral LNA-Based Drug Pact Gilead Adds to Fibrotic Disease Pipeline in \$202M Deal with LGLS Nektar Keeps Promotion Rights in \$175M Deal on Amikacin Drug Tobira Ramps up HIV Pipeline with Two Candidates and \$31M

#### Pain Deals

Amgen Sells Pain Molecule to J&J in \$385M Deal Encore, PainReform in Pain Collaboration Adolor Inks \$265M Deal with Pfizer for Opioid Alexza Licenses Inhaled Fentanyl Product To Endo; \$10M Up Front India's Glenmark in \$350M Deal with Lilly for Pain Compound Cephalon Acquiring Approved Muscle Relaxant for \$100M Icagen-Pfizer Deal: Potential \$1B-Plus for Pain Therapies Targacept NNR Platform Lands in Billion-Dollar GSK Alliance Hydra Lands Deal with Pfizer on Pain Drugs

#### **RNAi** Deals

Alnylam Signs Japanese Partner for RNAi-Based RSV Program Alnylam Signs Potential \$1B RNAi Agreement with Takeda Regulus, GSK Ink \$600M Deal for Drugs Targeting MicroRNA Source MDx Signs Pfizer to RNA-Based Biomarker Deal Alnylam, Merck Parting Ways; RNAi Stalemate Over at Last Alnylam, Medtronic Expand Deal with RNAi Drug-Device Combos Alnylam Captures Potential \$1B Roche Licensing Deal

#### Vaccine and Bacterial Disease Deals

Mpex, GSK in Antibiotics Deal Using Efflux Pump Inhibitors Emergent Adding FluBlok to Vaccine Arsenal in PSC Buy VaxGen Sells Anthrax Vaccine to Emergent for Potential \$10M Takeda Paying \$50M Up Front for GVAX in Prostate Cancer PharmAthene Buys Vaccines from Avecia in \$40M Deal Receptor Logic Finds Partner to Develop T-Cell Mimics Novexel in Deal for Beta Lactamase Inhibitor AmVac Signs Two Deals to Boost Vaccine Program Maxygen Licenses Antigens to Sanofi Group for \$24.5M Acambis Partners West Nile Vaccine in \$80M Sanofi Deal Merck Paying \$31M Up Front in Dynavax HBV Vaccine Deal Emergent Snags \$448M Deal for Anthrax Vaccine Intercell, Novartis Enter Pact

#### Mergers and Acquisitions

Ahead of OncoGenex Merger, Sonus Adds Caspase Program Clinical Data Boosts Pipeline with Adenosine Buyout BMS After ImClone; Offers \$60 per Share for Erbitux Partner Roche on a Roll; Getting Arius for \$190M \$125M Deal Sends Mirus Bio Into the Roche RNAi Camp Synergy Gets \$3M Offering; Callisto Gets Reverse Merger Roche \$43.7B Genentech Offer Makes Headlines Integration a Key Aspect of Roche/Genentech Proposal MacroGenics Boosts Anticancer Pipeline with Raven Acquisition Novartis Buying Speedel With Help of Top Brass ViroPharma to Acquire Lev Paying \$443M Up Front Access Expands Pipeline with MacroChem Merger SGX Shares Soar on Merger Giving Lilly Technology Boost Lilly Gets Discovery Partner SGX in a Deal Worth \$64M VGX Plans a Strategic Reverse Merger with Inovio Shire Paying Jerini \$519M for HAE Compound Firazyr BI Looking to Buy Actimis for \$515M if Asthma Drug Works

CytRx Rescues Innovive in \$25M Buyout, Adds Four Cancer Drugs Invitrogen, Applied Biosystems Join Forces in \$6.7B Merger Tercica Goes to Ipsen in \$663M Transaction \$400M Deal for Protez Gives Novartis Superbug Candidate Arno Gets \$18M Plus Market Access in Reverse Merger Gen-Probe Makes Counterbid for Diagnostics Firm Innogenetics Kosan's Cancer Pipeline Attracts \$5.50 Per Share BMS Buyout Bid Struggling Sonus Building Value, Pipeline via OncoGenex Merger Daiichi Sankyo to Purchase German Biotech for \$235M Bone Regeneration Product Brings in \$85M for Osiris Antisoma Boosts Pipeline with \$52M Xanthus Buy Cash-Strapped Iomai Jumps on \$189M Buyout Bid by Intercell Critical Therapeutics Investors Balk Over Cornerstone Merger Sepracor Forging Ahead in '08, on Oryx Buy GSK Grabbing Sirtuin Platform with \$720M Sirtris Acquisition Roche Buying Privately Held Piramed for \$160M Up Front Takeda Getting Millennium, Velcade in \$8.8B Cash Deal With No Partner and Little Cash, CeNeS Goes to Paion for \$21.9M Abraxis Buys Two Companies, Gets Cyclodextrin Platform Tekmira and Provita Merge to Form RNAi Powerhouse AVI Buying Ercole, Combining RNA Splicing Work, Portfolio EUSA Gains Commercial Status with \$22M Cytogen Purchase Pfizer Acquires Serenex for Undisclosed Amount CollaGenex Being Acquired by Galderma for \$420M Cash Cypress Buys into Personalized Medicine with \$75M Proprius Deal Pfizer \$195M Deal for Encysive Called a 'Good Deal' for Both Apex Bioventures Acquiring Dynogen in \$135M Stock Deal Isis Nets \$20M from Abbott for Share of Ibis Subsidiary Teva Buying HGS Spinout CoGenesys for \$400M Cash In \$57M Buyout, Invitrogen Adds Hepatocyte-Based Products Alkermes Gets \$166M Boost from GSK's Reliant Buyout CovX's Peptide-Antibody Bid Attracts Acquisition by Pfizer Biogen Fails to Attract Bids; Firm to Operate Independently Eisai Gaining Cancer Portfolio in \$3.9B MGI Acquisition ImmunoVaccine Nabs Immunotope Precision Therapeutics' IPO Set Aside; Merger Planned Amarin Obtains MRNA Platform, Phase II Drug Via Acquisition Astellas Buying into Cancer; \$387M Up Front for Agensys \$1.65B Deal for Reliant Boosts GSK Cardio Line Pfizer Boosts Vaccine Pipeline with \$164M Deal for Coley Celgene's \$2.9B for Pharmion Nets Hematology, Cancer Lines AstraZeneca Folds Cambridge Antibody into MedImmune Avant, Celldex Plan Merger; New Company Worth \$115M Cubist Gets Option to Acquire Illumigen; Funds HCV Drug Aspreva Ends Speculation with \$915M Acquisition

Orexo Acquires a Pipeline in \$133M Deal for Biolipox Dara, Point Therapeutics Join in Reverse-Merger Rescue QLT Buys Eye Device Firm for \$42M Plus Milestones Align Acquisition Pads Cyclacel's Resource Base Haptogen Acquisition Brings Shark Therapies to Wyeth PerkinElmer to Acquire ViaCell But Will Divest Cell Therapies Adnexus Nixes IPO Route, Opts for \$430M BMS Exit Virxsys Acquires Intronn, Gets RNA Payloads for Gene Therapy Evotec Plans Acquisition of Renovis in \$152M Stock Deal Nabi's 'Turnaround' Continues, Sells Biologics Unit for \$185M Entelos Adds Disease Models with the Acquisition of Iconix Upstream Completes Acquisition of Firm Focused on Parasites Cash-Poor IsoTis Acquired by Integra in \$51M Deal Aegera Acquires LymphoSign, Completes Series C Neuren Acquires Hamilton, Gets Phase II CNS Drug Cell Therapeutics Gets Phase II Cancer Drug in SMi Acquisition Merck Paying \$350M in Stock for Acquisition of NovaCardia Sanofi Building Vaccine Pipeline with \$549M Buyout of Acambis BMS After ImClone; Offers \$60 per Share for Erbitux Partner

#### Keys to Success

First Things First: Finding a Partner Are Biotechs Built to Prosper or Are They Built to be Sold? What Does Big Pharma Want? Tips When Thinking About Partnerships Reasons to Partner Tips for Negotiating the Deal Planning for Failure Avoiding Failure: Alliance Management Alliance Management the Eli Lilly Way After the Deal: Preparing for a Commercial Launch Challenges in Biopartnering Model Changing, But Alliances with Nonprofits Still Valuable

#### **Industry Interviews**

- An Interview with Greg Wiederrecht, Vice President and Head of the External Scientific Affairs Department of the Merck Research Laboratories, Merck & Co. Inc.
- An Interview with Warwick S. Bedwell, Vice President, Global Head of Business Development, Pharma Partnering, Roche
- An Interview with Robert L. Little, Vice President and Chief Commercial Officer, Halozyme Therapeutics Inc.
- An Interview with Kevin Giese, President and CEO, BioMS Medical Corp.
- An Interview with Safi R. Bahcall, President and CEO, Synta Pharmaceuticals Corp.
- An Interview with Todd Davis and Gregory Brown, co-founders and Managing Directors of Cowen Healthcare Royalty Partners

#### Partnering with Big Pharma and Big Biotech

Smart Partnerships: Filling Gap for Pharma, Financing Biotech Partnering Tables Turn as Big Pharma Pitches Biotech

Abbott Laboratories Alcon Inc. Amgen Inc. AstraZeneca plc Bayer Healthcare Pharmaceutical Biogen Idec Inc. Boehringer Ingelheim GmbH Bristol-Myers Squibb Co. Eisai Inc. Eli Lilly and Co. EMD Serono Inc. Genentech Inc. Genzyme Corp. GlaxoSmithKline plc H. Lundbeck A/S Jazz Pharmaceuticals Inc. Johnson & Johnson Merck & Co. Inc. Novartis AG Novo Nordisk A/S Nycomed A/S Organon International P&G Pharmaceutical Inc. Pfizer Inc. Roche Sanofi Pasteur Schering-Plough Corp. Shire plc Solvay Pharmaceutical Inc. Takeda Pharmaceutical Co. Ltd. TAP Pharmaceutical Products Inc. Wyeth

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#### Trends

Biotech Drug Approvals, 1982-2007 Forms of Alternative Financings **Deal Structures** Sources for Deals Venture Investing in 2007 Private Co. Financings Jan.-June 2008 Number of M&As Number of AgBio and Animal Deals Total Number of Biotech Deals Number of Biotech Collaborations with Universities and Nonprofits New Agreements Between Biotech and Big Pharma New Agreements Between Biotechs and Biotechs Number of Manufacturing, Marketing and Distribution Agreements Total Number of Biotech Deals, Including M&As IPOs and Follow-on Offerings: Amount Raised by Year Biotech M&A by Year: Announced Number of Transactions Biotech Deals: U.S. Mergers and Acquisitions Breakdown of Co-Development Deals by Stage Big Pharma Patent Expirations and Biotech Deals

Leading Pharma Companies' Revenue Loss from Patent Expiries Biotech Deals by Therapeutic Area Participation in BIO Investor and Partnering Events

Keys to Success Attributes of a Perfect Match Sources of Misalignment Range of Alliances The Foundations for a Successful Relationship Keys to Alliance Success Reasons for Alliance Failure Alliance Success Factors and Pitfalls Alliance Governance vs. Alliance Leadership Uncertainty in Life Sciences Deals Sample Radar Chart from Eli Lilly Model Reasons Behind the Increased Cooperation Between Industry and Academia for Partnerships Concerns for University Alliances

Company Name Estimated Value Date   Actelion Ltd.—GlaxoSmithKline plc \$3,200M 7/08   Isis Pharmaceuticals Inc.—Genzyme Corp. \$1,900M 1/08   Ablynx NV—Boehringer Ingelheim GmbH \$1,800M 9/07   Acceleron Pharma Inc.—Celgene Corp. \$1,800M 2/08   Targacept Inc.—GlaxoSmithKline plc \$1,570M 7/07   Galapagos NV—Janssen Pharmaceutica NV \$1,4300M 10/07   MacroGenics Inc.—El Lilly and Co. \$1,094M 10/07   Anlyam Pharmaceuticals Inc.—Roche Holding AG \$1,000M 7/07   Synta Pharmaceuticals Inc.—Sanofi-Aventis \$1,000M 11/07   Anylam Pharmaceuticals Inc.—Sanofi-Aventis \$1,000M 11/07   Angen Inc.—Takeda Pharmaceutical Co. Ltd. \$900M 2/08   Anisoma plc—Novatis AG \$890M 4/07   Seattle Genetics Inc.—Genentech Inc. \$860M 1/07   Renovo Group plc—Shire plc \$252M 6/07   Cytos AG—Novartis AG \$808M 4/07   ThromboGenies NV—F. Hoffmann-La Roche Ltd. \$780M 6/08   CoMentis Inc.—Astellas	Top Deals from 2007-2008			
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Alnylam Pharmaceuticals Inc.—Roche Holding AG\$1,000M7/07Synta Pharmaceuticals Inc.—GlaxoSmithKline plc\$1,000M10/07Regeneron Pharmaceuticals Inc.—Takeda Pharmaceutical Co.\$1,000M5/08Amgen Inc.—Takeda Pharmaceutical Co. Ltd.\$900M2/08Antisoma plc.—Novatis AG\$890M4/07Seattle Genetics Inc.—Genentech Inc.\$860M1/07Renovo Group plc.—Shire plc\$825M6/07Cytos AG—Novartis AG\$808M4/07ThromboGenics NV.—F. Hoffmann-La Roche Ltd.\$780M6/08CoMentis Inc.—Astellas Pharma Inc.\$760M5/08Tolerx Inc.—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals_Merck and Co. Inc.\$727M7/07Cytokinetics Inc.—Amgen Inc.\$702M1/07Addex Pharmaceuticals_Merck & Co. Inc.\$700M12/07Oxford BioMedica plc.—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Novartis AG\$600M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceuticals Inc.\$707M2/07Pharmaceuticals Inc.\$255M2/07Immunomedics Inc.—Novartis AG\$500M4/08Nastech Pharmaceuticals Inc.\$200M4/08Nastech Pharmaceuticals Inc.\$200M4/07State Corp.—Sanofi-Aventis\$525M2/07Regulus Therapeutics LLC—GlaxoSmi	Galapagos NV—Janssen Pharmaceutica NV	\$1,430M	10/07	
Synta Pharmaceuticals Corp.—GlaxoSmithKline plc\$1,000M10/07Regeneron Pharmaceuticals Inc.—Takeda Pharmaceutical Co.\$1,000M11/07Alnylam Pharmaceuticals Inc.—Takeda Pharmaceutical Co.\$1,000M5/08Amgen Inc.—Takeda Pharmaceutical Co. Ltd.\$900M2/08Antisoma plc.—Novatis AG\$890M4/07Seattle Genetics Inc.—Genentech Inc.\$860M1/07Renovo Group plc.—Shire plc\$825M6/07Cytos AG.—Novartis AG\$808M4/07ThromboGenics NV.—F. Hoffmann-La Roche Ltd.\$780M6/08Cohentis Inc.—Astellas Pharma Inc.\$760M5/08Tolerx Inc.—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals Inc.—Merck and Co. Inc.\$727M7/07Cytokinetics Inc.—Amgen Inc.\$700M12/07Addex Pharmaceuticals—Merck & Co. Inc.\$700M12/07Oxford BioMedica plc.—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Novartis AG\$600M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceuticals Inc.\$77M2/07Pharmaceuticals Inc.\$70M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceuticals Inc.\$70M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceuticals Inc.\$70M2/07 </td <td>MacroGenics Inc.—Eli Lilly and Co.</td> <td>\$1,094M</td> <td>10/07</td>	MacroGenics Inc.—Eli Lilly and Co.	\$1,094M	10/07	
Regeneron Pharmaceuticals Inc.—Sanofi-Aventis\$1,000M11/07Alnylam Pharmaceuticals Inc.—Takeda Pharmaceutical Co.\$1,000M5/08Amgen Inc.—Takeda Pharmaceutical Co. Ltd.\$900M2/08Antisoma plc—Novatis AG\$890M4/07Seattle Genetics Inc.—Genentech Inc.\$860M1/07Renovo Group plc—Shire plc\$825M6/07Cytos AG—Novartis AG\$808M4/07ThromboGenics NV—F. Hoffmann-La Roche Ltd.\$780M6/08CoMentis Inc.—Astellas Pharma Inc.\$760M5/08Tolerx Inc.—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals Inc.—Merck and Co. Inc.\$727M7/07Cytokinetics Inc.—Amgen Inc.\$702M1/08Santaris Pharma A/S—GlaxoSmithKline plc\$700M12/07Oxford BioMedica plc—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Nycomed GmbH\$600M12/07MorphoSys Inc.—Novartis AG\$600M12/07Nastech Pharmaceutical Co. Inc.—Procter & Gamble\$577M2/07Pharmaceuticals Inc.\$2083/08Argent Discovery Ltd.—AstraZeneca plc\$500M9/07GTx Inc.—Kovaw Hakko Kogyo Co. Ltd.\$520M3/08Argenta Discovery Ltd.—AstraZeneca plc\$500M9/07GTx Inc.—Merck & Co. Inc.\$500M9/07Argenta Discovery Ltd.—AstraZeneca plc\$500M9/07GTx Inc.—Merck &	Alnylam Pharmaceuticals Inc.—Roche Holding AG	\$1,000M	7/07	
Alnylam Pharmaceuticals Inc.—Takeda Pharmaceutical Co.\$1,000M5/08Amgen Inc.—Takeda Pharmaceutical Co. Ltd.\$900M2/08Antisoma plc—Novatis AG\$890M4/07Seattle Genetics Inc.—Genentech Inc.\$860M1/07Renovo Group plc—Shire plc\$825M6/07Cytos AG—Novartis AG\$808M4/07ThromboGenics NV—F. Hoffmann-La Roche Ltd.\$780M6/08CoMentis Inc.—Astellas Pharma Inc.\$760M5/08Tolerx Inc.—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals Inc.—Merck and Co. Inc.\$727M7/07Cytokinetics Inc.—Amgen Inc.\$702M1/07Addex Pharmaceuticals—Merck & Co. Inc.\$702M1/07Addex Pharmaceuticals—Merck & Co. Inc.\$700M12/07Oxford BioMedica plc—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Nycomed GmbH\$600M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceuticals Inc.\$77M2/07Pharmaceuticals Inc.\$225M2/07Immunomedics Inc.\$77M2/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceutical Inc.\$220M3/08Argenta Discovery Ltd.—AstraZeneca plc\$500M2/07Radius Health Inc.—Novartis AG\$500M9/07GTx Inc.—Merek & Co. Inc.\$500M	Synta Pharmaceuticals Corp.—GlaxoSmithKline plc	\$1,000M	10/07	
Amgen Inc.—Takeda Pharmaceutical Co. Ltd.\$900M2/08Antisoma plc.—Novatis AG\$890M4/07Seattle Genetics Inc.—Genentech Inc.\$860M1/07Renovo Group plc.—Shire plc\$825M6/07Cytos AG.—Novartis AG\$808M4/07ThromboGenics NV.—F. Hoffmann-La Roche Ltd.\$780M6/08CoMentis Inc—Astellas Pharma Inc.\$760M5/08Tolerx Inc—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals Inc—Merck and Co. Inc.\$727M7/07Cytokinetics Inc—Amgen Inc.\$725M1/07Addex Pharmaceuticals—Merck & Co. Inc.\$722M1/08Santaris Pharma A/S—GlaxoSmithKline plc\$700M12/07Oxford BioMedica plc—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Nycomed GmbH\$620M1/08MorphoSys Inc.—Novartis AG\$600M12/07Pharmaceuticals Inc	Regeneron Pharmaceuticals Inc.—Sanofi-Aventis	\$1,000M	11/07	
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Renovo Group plc—Shire plc\$825M6/07Cytos AG—Novartis AG\$808M4/07ThromboGenics NV—F. Hoffmann-La Roche Ltd.\$780M6/08CoMentis Inc.—Astellas Pharma Inc.\$760M5/08Tolerx Inc.—GlaxoSmithKline plc\$750M10/07Ariad Pharmaceuticals Inc.—Merck and Co. Inc.\$727M7/07Cytokinetics Inc.—Amgen Inc.\$725M1/07Addex Pharmaceuticals—Merck & Co. Inc.\$702M1/08Santaris Pharma A/S—GlaxoSmithKline plc\$700M12/07Oxford BioMedica plc—Sanofi-Aventis SA\$690M3/07XenoPort Inc.—GlaxoSmithKline plc\$640M2/07Anacor Pharmaceuticals Inc.—Schering-Plough Corp.\$625M2/07Immunomedics Inc.—Nycomed GmbH\$6600M12/07Regulus Therapeutics LLC—GlaxoSmithKline plc\$600M4/08Nastech Pharmaceutical Co. Inc.—Procter & Gamble\$577M2/07Pharmaceuticals Inc.\$207Margen Inc.—Kyowa Hakko Kogyo Co. Ltd.\$525M2/07Regulus Health Inc.—Novartis AG\$500M2/07Radius Health Inc.—Novartis AG\$500M2/07Radius Health Inc.—Novartis AG\$500M2/07Radius Health Inc.—Novartis AG\$500M9/07GTx Inc.—Merck & Co. Inc.\$500M1/07Adata Laberta Sanda Sa	Antisoma plc—Novatis AG	\$890M	4/07	
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Source: BioWorld Today archives.	Source: <i>BioWorld Today</i> archives.		,	

## **Executive Summary**

#### Biopartnering Isn't Just Facilitating the Drug Industry; It Is Delineating It

Biopartnering is big in 2008. It is big like DNA in 1953 ... big like Genentech in 1976 ... big like human insulin in 1982 ... big like the Human Genome Project in 2001.

It is big like the driver of an \$80 billion revenue biotechnology market that is capable of facilitating ultramodern research to manage, or potentially eradicate, disease in a number of indications, while buttressing the bottom lines of not one, but two, principal mega-markets.

The biopartnering dynamic is attracting the fancy and finances of the \$700 billion pharmaceutical industry and infusing the biotechnology market with the pecuniary and material resources necessary to increase its collective market status into the \$100 billion value range.

If there is one thing that is apparent, albeit not exclusive, in biotech, it is that things change, and changing dynamics have usually resulted in unexpected, but more often than not, ultimately positive results for the overall biotech market. The ongoing biopartnering relationship with the pharmaceutical industry is the latest, and arguably, the most impactful, lifeline dynamic in biotech's history.

The fragile dollar, the stagnate European biotech market, a foreboding prevalence of global disease, the nascent Asian life sciences sector, the meandering overseas pharma industry, and the withstanding biotechnology market are acting together in creating a perfect storm of opportunity to partner or invest in American biotech.

The engine that drives this phenomenon is the innovation that the biotechnology sector has historically and continuously demonstrated through periods of traditional investment droughts, irresolute regulatory administration, protracted research agendas, demanding stockholder impatience, and its own oft-sparse cash reserves.

#### When Does a Trend Become a Standard?

There has been no abatement in 2008 in the level of biopartnering activity that swept through and buttressed the biotech and pharma markets in 2007. Deals continue to overshadow drugs and venture capital investment as the defining industry trend, as biopartnering transactions continue at record-breaking occurrence rates and financial levels, while annual FDA approval rates remain flat and VC financings are losing the steam they had maintained throughout the first half of 2008.

The deal is still the thrill in drug development markets, as biotechnology innovation continues to be the temptation from which Big Pharma cannot afford to abstain.

A developing twist is being observed, as Big Pharma is getting increased competition from secondary suitors in courting biotech. Entities such as nonprofit/patient advocacy organizations, CROs, academia and government bodies are joining in to vie for the attention of biotech's innovative projects. The participation of these groups is contributing to increase the number of late-stage deals, while concurrently decreasing the number of available late-stage clinical opportunities, thereby making it more necessary to consider strategies that delve deeper into the pipeline to secure deals or bankroll projects that are in earlier stages of development.

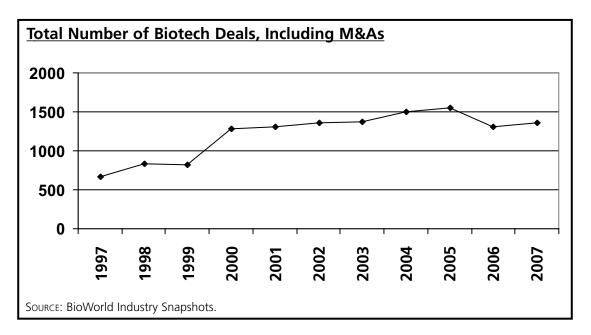
This trend is giving a financial boost to platform, preclinical and Phase I programs that have heretofore been generally shunned by picky investors preferring to minimize their risks and ROI waiting periods by backing projects that are closer to commercialization.

Much is at stake, as evidenced by the record amount of \$168 million spent on lobbying by the drug development industry in 2007, representing a 32 percent jump over 2006. The pharmaceutical industry continues to lead all markets in lobbying dollars, which translate into political results, meaning Big Pharma usually gets what it wants, and, right now, pharma wants biotech!

Who ever thought the exit strategy for the biotechnology market would culminate in a "rule the world" scenario? We are not projecting that the pharmaceutical industry is financing its own demise, as the biopartnering trend is definitely mutually beneficial; however, the lasting regard will likely reside with the innovators, rather than the financiers. "Who cured diabetes?" will generally eclipse "Who paid for the research?"

A concern in the biopartnering phenomenon is that the biotech industry will be compromised, or summarily assimilated into the pharmaceutical industry, consequently losing its aptitude for innovation under the aegis of Big Pharma. That apprehension may be assuaged when observing the prevailing trend of pharmas seeking to be more like biotech, rather than trying to meddle with the success of innovation by attempting to instill the pharma culture into its new partners or acquisitions.

Much to their credit, big pharmaceutical companies, such as Roche, GlaxoSmithKline and Bristol-Myers Squibb are going out of their way to adopt the mentality and tactics of the biotech milieu in order to



cultivate the environment of innovation that currently is the almost-exclusive territory of biotech.

These companies are changing their management, R&D agendas, investment objectives and even the way they refer to themselves, as they willingly and unabashedly reinvent themselves in the image of their junior counterpart market.

Well, the more pharma companies seek to shed their proper pharmaceutical corporate trade names and insist on a.k.a. designations such as "biopharmaceutical," "biotherapeutics," "drug development," "bioscience," "health care," or anything other than their "pharma" surnames, the more it signals a shift in the rise of biotechnology's regard, clout, value and deed. This does not signal the downfall of the pharmaceutical industry, rather the mutually constructive integration of the two markets into a therapeutic and financial entity that can exploit, manage and facilitate therapeutic innovation from concept through commercialization.

That process has traditionally been divided between the two industries, with biotech doing the front-end brainwork in academia and early-stage to create and develop unique therapeutics, and pharma using its resources arsenal to do the heavy lifting on the back end to deliver marketable products. This biopartnership archetype that exploits the strengths of all components is defining the new face of an integrated drug development market that will produce the therapeutics of the twenty-first century.

This progressive confluence is seeing each side engage in and, consequently, become more proficient in each other's strong suit, as the bigger, and even some mid-sized, biotechs increasingly commercialize their own products with little or no Big Pharma help, while Big Pharma evermore gets involved in the earlier phases of the drug development cycle, as competition for late-stage therapeutic programs intensifies.

Even so, it may be unwarranted to criticize Big Pharma's precautious approach, considering its tactic of selectivity in waiting for a technology or clinical trial to reach its "safest bet" stage has afforded it the ability to avoid being burned by the failure of others as much as, say, its counterparts in the traditional VC community.

On the other hand, pharma's reluctance to embrace early-stage deals leaves that opportunity open for alternatives to Big Pharma's financing, such as nonprofits and individual investors.

In spite of spotting the pharmaceutical industry a century-long head start in drug development, it is conceivable that the biotechnology therapeutics market could surpass pharma's record of curing disease within a period as soon as the next decade. Such a feat would be primarily attributable to the many never-before-seen, but imminently on-the-market (as projected by BioWorld analysis) technologies and products developed from the pipelines of biotech companies, and also from the pharma entities that are capitalizing on the biopartnering opportunities that are now available.

#### Biopartnering's Big Challenge Could Be Big Pharma's Impatience

The foremost challenges to the continuation of the biopartnering trend will not be posed by financial or innovation shortages, but will be most prone to result from the impatience of Big Pharma in waiting out the tenure of traditionally slow clinical trial cycles, especially when partnering deals involve earlier-stage candidates that may be four of more years from realistically reaching the market.

Unfortunately, Big Pharma and venture capitalists still seem to lack corresponding confidence in innovation, as evidenced by their persistent reluctance to earnestly support the early-stage research that is the seed for the eventual bloom that winds up on the market.

It should be acknowledged that pharma's predilection for the deal is not necessarily an altruistically driven mission; rather, it is at least partially spurred by its own inability to sustain an in-house innovative R&D environment. That shortcoming is responsible for the creative stalls in pharmaceutical pipelines that are threatening to produce corresponding stalls in revenue generation beginning in earnest around 2011-2012, when some of the industry's top-selling pharmaceutical drugs are scheduled to be exposed to generic competition.

Still today, relative to the biopartnering trend, the pejorative attitude in pharma toward early-stage remains the biggest potential derailing factor that could wreck the abiding biotechnology archetype.

In contrast, as far back as its origin, biotechnology has acknowledged the fact that innovation takes time to develop and that discovery is just as important as the product. Innovation doesn't grow on trees, but it does mature as deliberately as a tree.

If biopartnering deals persist, they are likely to consume many, if not all, Phase III biotech projects. Especially if M&As are included in biopartnering activity, the ripe projects will be picked and harvested even more quickly under the auspices of pharma buyers looking for sooner-than-later ROIs.

Pharma's impatience will be tested when it is time to make the decision whether to curtail the biopartnering trend or seriously engage in early-stage deals that would be expected to primarily safeguard the future by nurturing projects that would be available to replace the next wave of products that will fall victim to patent expirations around the latter part of the next decade.

The pharmas seem to be paying attention now, but even though they may acknowledge the largely self-inflicted reasons behind the mess they are in currently, (but may wind up evading anyway, due to the SOS biopartnering deals being made) it is not a given that they have sufficiently conquered their early-stage phobia.

Unless Big Pharma can permanently take on that part of the biotech mind-set that respects the front-end of drug development as dutifully as the end product, funding gaps for those R&D stages will produce correlated revenue disruptions years later.

#### Late-Stage Projects Being 'Spoiled Rotten,' While Newborn Ones Must 'Act Out' for Attention

Pharma is saying complimentary things now about not stymieing biotech's creative spirit and managing such acquisitions and partnerships in a hands-off style; however, it will take plenty of rarelyseen-before early-stage patience on pharma's behalf for those sound bites to become manifest. Pharma, which is a first-born in the drugmaker family itself, has, in turn, conventionally showed favoritism to the eldest pipeline offspring, investing in their near-future and bestowing them with full access to the parent's vast accumulative resources.

The biopartnering trend is seeing biotech giving pharma more heirs to propagate and extend its dynasty, and the eldest of those are getting the true-to-form preferential treatment that has been pharma's trademark. Once the most senior of these adopted technologies leave the pipeline nest for market, however, pharma's next likely, and best, option is apt to be to focus its usually short attention span on the remaining junior candidates in Phase I and earlier in order to rear those stepchild candidates into enough maturity to live on their own in the marketplace.

Many ongoing trends and best business practices will continue to be relevant into 2009, including:

- M&As
- Approaching/Getting noticed by Big Pharma
- Alternative financings and sources
- Alliance management
- Terms sheets and agreements
- Gene therapy deals
- Government, private and individual stem cell financings

Major new trends through 2009 include:

• An increase in the number of entities shopping for biotech. Biotechnology companies don't have to peddle themselves or their technologies as aggressively as they did earlier in the decade. This is attributable to the pipeline problems that are requiring pharmaceutical companies to redirect their business operations to mimic biotech (fewer employees, more focused R&D approaches that include fewer indications, more integration of biotech platforms into existing clinical trials, etc.).

• More sponsorship and funding of biotech R&D by non-pharma sources, particularly non-profits (in less prevalent disease indications), government (state-level support of stem cells, agbio, biofuels, etc.).

• The gradual return of traditional VC investment in biotech. Pharma is getting the bulk of late-stage candidates. Given the VCs' aversion to front-end research, it is likely that they will seek to invest in the best of the remaining projects that are within three years of potential market launches, as Big Pharma shows no sign of slowing down in its biotech mission. That will require their participation sooner, rather than later, so a return of the traditional VC could begin as early as the beginning of 2009.

Note: This Executive Summary is reprinted from *The BioWorld BioPartnering Report: Strategies and Paradigms of the Deal*, published by AHC Media LLC. Copyright © 2008. For more information or to order a report, please visit www.bioworld.com.

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