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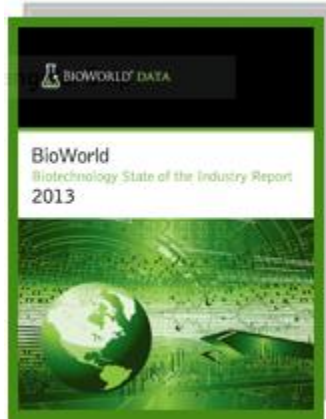
BioWorld

Biotechnology State of the Industry Report 2013



BioWorld's Biotechnology State of the Industry Report 2013

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This *State of the Industry Report* brings you the defining moments from the past year; it's your GPS to the future showing you the roads that will help lead you to continued growth and bottom line security. It highlights the highs, puts the lows into perspective, and delivers actionable business information for 2013 and beyond.

Our respected and accomplished writers map out the trends, uncover the products, deals, litigation, R&D, financial forecasts, and all the factors that have defined the biotech market in this past year into one concise report that will be delivered to you in both print and PDF formats. With in-depth analysis into emerging markets; the impact of the European market; regulatory, political and Wall Street insights, the *State of the Industry Report* is the market research you'll turn to again and again.

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Analysis	11
Post-Recession Economy Sets Stage for Reconstruction Era	13
Receptive Markets, But Fundraising Still a Challenge.....	15
Not a Lot of Certainty for Biopharma in Much of 2012	18
Testing Times as Austerity Grinds on, Pharma Markets Fall	21
Is There Madness to the Method?	24
Financial Data	27
Corporate Deals	105
Fewer but Larger M&A Deals in 2012 Suggest Biotechs Gaining Market Leverage	107
Report Card for Wall Street	305
Stock Performance	317
Restructurings	323
Lawsuits	331

Analysis	11
Financial Data	27
Biotech Money Raised by Month in 2012.....	29
Initial Public Offerings of Biotechnology in 2012.....	30
Biotechnology Follow-On Offerings in 2012.....	32
After-Market Performance: IPO Class of 2012.....	41
After-Market Performance: Follow-On Offerings Class of 2012.....	42
2012 Initial Public Offerings.....	45
2012 Follow-on Offerings.....	45
Gross Proceeds of Biotech Public Stock Offerings.....	46
Biotech Money Raised: 1997-2012.....	47
Nasdaq Stock Index 2012.....	48
BioWorld Stock Index 2012.....	48
Other Financings of Public Biotechnology Companies in 2012.....	49
Venture Capital and Other Investments in Private Biotechnology Companies in 2012.....	70
Milestone Payments from Corporate Partners in 2012.....	85
Grants and Awards Given to Biotech Companies in 2012.....	91
Corporate Deals	105
Top Bio/Pharma Deals Of 2012.....	111
Top 10 Life Sciences M&As: 2012.....	112
Top Deals Between Biotech Companies: 2012.....	113
Biotech Mergers and Acquisitions in 2012.....	114
Biotechnology Company Deals with Pharmaceutical Companies in 2012.....	121
Modified Deals Between Biotechs and Pharmas in 2012.....	151
Terminated Deals Between Biotechs and Pharmas in 2012.....	156
Manufacturing/Supply/Distribution Deals Between Biotechs and Pharmas in 2012.....	160
Biotechnology Company Deals with Other Biotechnology Companies in 2012.....	171
Biotech–Biotech Collaborations: Modified Agreements for 2012.....	200
Biotech–Biotech Collaborations: Terminated Agreements in 2012.....	203
Collaborations Between Biotechnology Companies and Government/Nonprofit Institutions in 2012.....	205
Manufacturing, Marketing and Distribution Agreements Between Biotech Companies in 2012.....	228
Biotech Product Development.....	237
Biotechnology Products Approved by The FDA in 2012.....	239
Biotech Products 1982-2012 A-Z.....	245
FDA Actions on Pending Applications in 2012.....	274
Licensing Applications Filed and Pending at FDA in 2012.....	277
Recommendations by FDA Advisory Panels in 2012.....	284
Non-U.S. Approvals and Other Regulatory Actions in 2012.....	287
Orphan Designations Granted in 2012.....	299

Report Card for Wall Street	305
U.S. Public Offering Performance by Underwriter: Jan. 1 - Dec. 31, 2012.....	307
U.S. Public Offering Performance by Underwriter: Jan. 1 - Dec. 31, 2012.....	309
Lead Underwriter Performance on All U.S. Offerings: Jan. 1 - Dec. 31, 2012.....	311
Lead Underwriter Performance on All U.S. Offerings: Jan. 1 - Dec. 31, 2012.....	312
Underwriters' Performance on IPOs: Jan. 1 - Dec. 31, 2012	313
Underwriters' Performance on IPOs: Jan. 1 - Dec. 31, 2012	313
Underwriters' Performance on IPOs: Jan. 1 - Dec. 31, 2012	314
Underwriters' Performance on IPOs: Jan. 1 - Dec. 31, 2012	315
Stock Performance	317
2012 U.S. Biotechnology Stock Report	319
2012 British Biotechnology Stock Report	321
2012 Canadian Biotechnology Stock Report.....	322
Restructurings	323
Biotech Restructurings, Scale-Backs, Bankruptcies: Jan. 1 - Dec. 31, 2012	325
Lawsuits	331
Biotech Lawsuits: Jan. 1 - Dec. 31, 2012	333

Biotech to Rise Again – but Different

Post-Recession Economy Sets Stage for Reconstruction Era

By Jennifer Boggs
Managing Editor

If the pre-recession biotech industry was the equivalent of the Old South, then the past few years were like the Civil War, tearing through the sector and leaving the traditional funding and growth models in smoking ruins.

With 2012 came the beginning of an era of reconstruction, with the sector finally accepting the “new normal” state of the economy and, for the first time, actively assembling alternatives to the mostly-no-longer-feasible financial and productivity strategies of old.

Long gone are the days when a biotech start-up could line up financial backers with nothing but discovery research and a promise; when a big pharma firm would shell out big bucks for an early stage asset; when every piece of news – the start of a midstage trial or the hiring of a new exec – would send biotech shares hopping.

But maybe that’s not really a bad turn of events.

After all, it was bound to happen sooner or later; the recession might just have accelerated the sector’s evolution. As biotech moves into its fourth decade, the industry has become more mature. The harsh realities of drug development – increasing costs, limited capital and regulators skittish in the wake of previous safety snafus – have tempered the once-rampant blind optimism. And what remains promises to be leaner, smarter and perhaps more innovative than ever.

Signs of that innovation emerged in 2012. While the sector’s overall fundraising dropped off for the year – down 22.4 percent from 2011 figures – companies tended toward more of the alternative funding models such as at-the-market financings, debt financings and royalty agreements. And more options are set to open up to biotech in the future, thanks to the passage of the Jumpstart our Business Startups (JOBS) Act.

JOBS is expected to offer a significant impact on small firms by providing new fundraising avenues such as crowdsourcing and by easing compliance with securities laws, though the industry is still awaiting final implementation by the SEC.

The year saw creativity in dealmaking, too. Though the number of both M&A transactions and partnership agreements fell between 2011 and 2012, the deal values increased. M&A deals, for instance, averaged \$78.6 million for the year, an 18.5 percent jump over 2011, an impressive feat particularly considering the absence of any mega-mergers in 2012 to skew the numbers higher.

Acquirers continued to take advantage of earn-outs and contingent value rights to bridge the value gaps, and

the good news was that up-front payments in those deals trended higher in 2012 compared to the previous year.

But the award for most inventive transaction of the year easily went to Amylin Pharmaceuticals Inc.’s \$7 billion buyout via collaboration: Bristol-Myers Squibb Co. took the lead, purchasing Amylin’s stock for \$5.3 billion and settling a \$1.7 billion obligation, before AstraZeneca plc came on board to partner on Amylin assets for \$3.4 billion. The arrangement proved a win-win, assuaging Amylin’s board, which had been rumored to have rebuffed an earlier, lower offer from BMS, while spreading the risk between the two pharmas.

Overall, stocks trended upward over the year, with the Nasdaq Biotechnology Index gaining 32 percent, the AMEX Biotechnology Index jumping 41.7 percent and the composite Nomura Code Euro Biotech Index gaining 26 percent on the year. Biotech’s top four large-caps – Amgen Inc., Biogen Idec Inc., Celgene Corp. and Gilead Sciences Inc. – all had solid stock growth, with Gilead’s stock posting the largest gain for the year at 79.4 percent, largely driven by positive hepatitis C data from newly acquired Pharmasset Inc.

On the regulatory front, 2012 also brought good news. Drug approvals were up from 2011 – a whopping 39 drugs gained the FDA’s blessing. And Congress passed – with minimal bipartisan fuss and ahead of its self-imposed deadline – the FDA Safety and Innovation Act, which provided the much-needed regulatory guidelines and created new user fees. It also included incentives for firms working in the antibiotics and rare disease spaces.

And as blockbuster drugs began dropping off the patent cliff, big pharma began seeking out new initiatives to bolster early research and tackle productivity woes, including efforts to open up research. Last year saw the launch of nonprofit TransCelerate BioPharma Inc., with 10 of the industry’s largest pharma firms on board, aimed at improving the speed and quality of clinical trials by identifying and solving bottlenecks in trial design and execution.

Other programs include an open innovation approach to R&D pledged by GlaxoSmithKline plc to allow researchers access to detailed patient-level data underlying clinical trials of approved drugs and failed compounds. And, with an official launch in February 2013, the Innovative Medicines Initiative kicked off in Europe with a €196 million (US\$266 million) project in which seven pharma companies will make at least 300,000 compounds available for screening via an open platform.

That’s the good news.

The bad is that there are myriad challenges ahead, starting with some deep budget cuts. The FDA and the National Institutes of Health face slashed funding due to sequestration, while the European economy is dealing with the continuation of austerity, which so far has contributed to dramatic cutbacks to both biotech and pharma firms alike.

Blockbusters continue tumbling off the patent cliff, with few prospective replacements coming down the pike; venture capital remains as hard to come by as ever; translational medicine's "Valley of Death" keeps getting wider; and companies are still waiting to see how the patent reform legislation will affect their intellectual property and overall value.

Plus, biotechs are still struggling with commercialization,

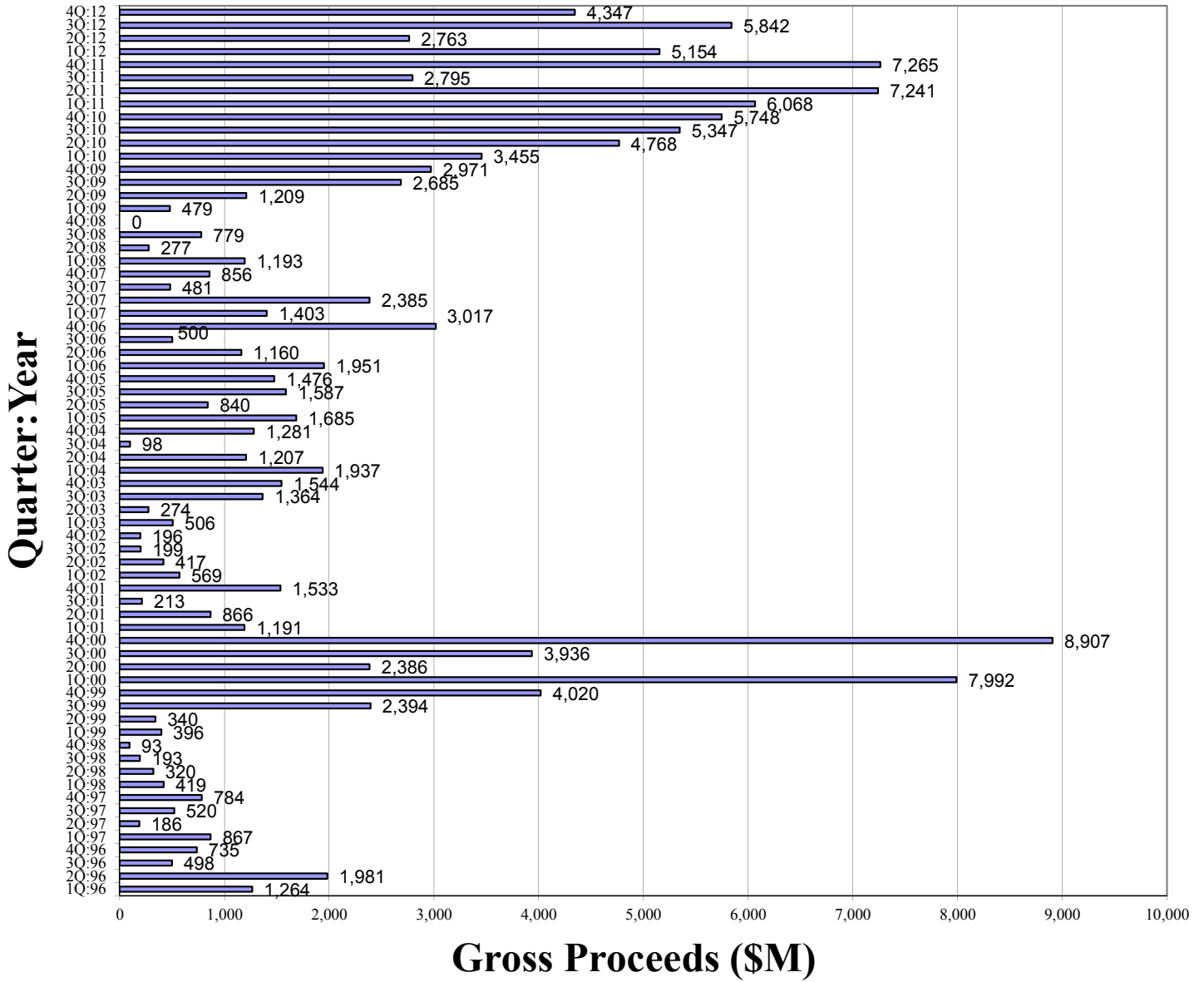
which has proved one of the maturing industry's biggest bugaboos, as an increasing number of firms enter the market without the added muscle from big pharma partners. Vivus Inc., for example, faced some harsh criticism from analysts following its fourth-quarter 2012 earnings in which obesity candidate Qsymia (phentermine/topiramate) fell short of sales expectations.

Figuring out how to get its innovative drugs to patients will go a long way to securing the sector's future growth.

But just as the post-Civil War Reconstruction Era eventually transformed the Old South into the New South, the region shedding its agrarian ways in favor of industrialization, the biotech industry, too, will need to continue evolving if it wants to advance the research and development vital to addressing unmet medical needs.

Gross Proceeds of Biotech Public Stock Offerings

First Through Fourth Quarter 1996-2012 Initial and Follow-on Offerings Combined



Venture Capital and Other Investments in Private Biotechnology Companies in 2012

TOTAL: \$3,852.7M

Company	Location	Amt. (M)	Details	Date
JANUARY				
3-V Biosciences Inc.	Menlo Park, Calif.	\$20	3-V Biosciences closed a preferred stock financing providing a minimum of \$20M with existing investors Kleiner Perkins Caufield and Byers and New Enterprise Associates	1/6/12
Apogenix AG	Heidelberg, Germany	€7.5 (\$9.6)	Apogenix raised \$9.6M in a Series C investment from Dievini Hopp BioTech Holding GmbH & Co. KG, the German Cancer Research Center and the company's founders and management	1/6/12
Avexxin AS	Trondheim, Norway	ND	Avexxin closed an undisclosed Series A round; Sarsia Seed managed the investment in syndication with Leiv Eiriksson Invest	1/10/12
BergenBio AS	Bergen, Norway	\$8.8	BergenBio raised \$8.8M in a Series A round from Sarsia Seed AS and Investinor AS	1/10/12
BioRelix Inc.	New Haven, Conn.	\$0.5	BioRelix received \$500,000 from Connecticut Innovations as part of a \$4.2M round of funding	1/19/12
Blend Therapeutics Inc.	Watertown, Mass.	ND	Blend raised an undisclosed amount from Flagship Ventures, New Enterprise Associates and NanoDimension	1/9/12
Clearside Biomedical Inc.	Atlanta	\$4	Clearside launched with a \$4M Series A from Hatteras Venture Partners	1/6/12
CrystalGenomics Inc.	Pangyo, South Korea	KRW3B (\$2.6)	CrystalGenomics raised \$2.6M through a private placement to the Korea Seoul Life Science Fund	1/17/12
Elevation Pharmaceuticals Inc.	San Diego	\$30	Elevation raised \$30M in a Series A round led by Novo Ventures, and including Canaan Partners, TPG Biotech, Care Capital and Mesa Verde Venture Partners	1/5/12
Galecto Biotech AB	Lund, Sweden	ND	Galecto received seed funding from Novo A/S, Merck Serono Ventures and Forskarpatent	1/4/12
MacuClear Inc.	Plano, Texas	\$1	MacuClear secured more than \$1M in funds from current investors	1/4/12
MedGenesis Therapeutix Inc.	Victoria, British Columbia	\$5	MedGenesis raised \$5M from undisclosed sources for Phase II trials of its Parkinson's therapy	1/11/12
Midatech Ltd.	Oxford, UK	£6.3 (\$9.76)	Midatech raised \$9.76M through a private investment round	1/6/12
Oxford Cancer Biomarkers Ltd.	Research Triangle Park, N.C.	£3 (\$4.68)	Quintiles Transnational Corp. invested \$4.68M to gain a 27.5% stake in Oxford Cancer Biomarkers	1/25/12
Pharmalink AB	Stockholm, Sweden	SEK35 (\$5.1)	Pharmalink raised \$5.1M through a rights issue of new shares to existing shareholders, including Industrifonden	1/5/12
Probiodrug AG	Halle, Germany	€15 (\$19.4)	Probiodrug raised \$19.4M from investors BB Biotech, Edmond de Rothschild Investment Partners, Life Sciences Partners, Biogen Idec New Ventures, TVM Capital, HBM BioVentures, Goodvent/IBG and private investors	1/5/12

Biotech Mergers and Acquisitions in 2012

TOTAL VALUE IN 2012: \$55,123M*

DISCLOSED UP-FRONT PAYMENTS IN 2012: \$29,304M

DISCLOSED MILESTONE PAYMENTS IN 2012: \$5,440M

NUMBER OF M&As IN 2012: 69

Company Acquired (Location)	Acquired By Or Merged With (Location)	Date Reported	Date Completed*	Value (M)@	Terms/Details
JANUARY					
Oncogenerix Inc. (South Carolina)	DARA BioSciences Inc. (Raleigh, N.C.)	1/18/12	1/18/12	ND	DARA acquired Oncogenerix and U.S. rights to sell Soltamox for breast cancer for an undisclosed amount
Pharmasset Inc. (Princeton, N.J.)	Gilead Sciences Inc. (Foster City, Calif.)	11/22/11	1/19/12	\$11B	Gilead offered to pay \$137 per share in cash; Pharmasset's board unanimously approved the transaction and 95% of Pharmasset's outstanding shares were validly tendered by mid-January
Scil Technology GmbH (Martinsried, Germany; subsidiary of BioNet Holding)	Nanohale AG (Dortmund, Germany)	1/10/12	1/10/12	ND	Nanohale acquired the research and development, contract development and manufacturing organization of Scil in an asset deal
FEBRUARY					
ADMA Biologics Inc. (Hackensack, N.J.)	R&R Acquisition VI Inc.	2/15/12	2/15/12	ND	ADMA completed a reverse merger with publicly held R&R Acquisition VI Inc.
Aldagen Inc. (Durham, N.C.)	Cytomedix Inc. (Gaithersburg, Md.)	2/9/12	2/9/12	\$16	Cytomedix issued 135,398 shares of Series E preferred stock, valued at \$16M, to acquire Aldagen
Enobia Pharma Corp. (Montreal)	Alexion Pharmaceuticals Inc. (Cheshire, Conn.)	12/28/11	2/8/12	\$1B	Alexion bought Enobia for \$610M up front and \$470M in sales and regulatory milestones
Inhibitex Inc. (Alpharetta, Ga.)	Bristol-Myers Squibb Co. (New York)	1/10/12	2/14/12	\$2.5B	BMS completed its tender offer of \$26 per share, or \$2.5B, to acquire Inhibitex, which it will operate as a wholly owned subsidiary
Scarista Ltd. (UK)	Prismic Pharmaceuticals Inc. (Scottsdale, Ariz.)	2/8/12	2/8/12	ND	Prismic acquired the assets of Scarista for an undisclosed amount
MARCH					
Avila Therapeutics Inc. (Bedford, Mass.)	Celgene Corp. (Summit, N.J.)	1/27/12	3/9/12	\$935	Celgene paid \$350M in cash, plus up to \$195M for milestones related to AVL-292, and up to \$280M in milestones contingent upon development and approval of candidates generated from Avila's Avilomics platform