Innovation, Business Strategies and Stock Returns in Biotechnology Industry

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Abstract

The paper analyzes the impact of small biotechnology firms' innovation and business strategies on their stock returns utilizing event study methodology. These are some of the conclusions supported by the empirical results: (i) firms should focus on regulatory approval of their products; (ii) it is important to recruit individuals and consulting firms with valuable specialized expertise in field; (iii) firms should pursue licensing and manufacturing deals aggressively; and (iv) firms should be highly selective and careful with deals they make for R&D collaboration with scientific community. The implications could be valuable to managers of startup firms in this particular industry and possibly in others, as well as for understanding how financial markets react to innovation announcements.

Keywords: innovation, event study, abnormal daily returns, stock returns, pharmaceutical, biotechnology, R&D, FDA approvals

JEL Classification: C22; G14; I11

1. Introduction

The objective of this paper is to measure the impact of the startup biotechnology firm's strategies and innovations on its stock value during its initial stages of growth (at least first 10 years). The implications could be valuable to managers of startup firms in this particular industry or possibly in others, as well as for understanding how markets react to innovation announcements. Moreover, survival of a new public firm depends on many factors, but few are observable to study and to draw conclusions from. Stock market data combined with actions taken by firms has been used by researchers to sort through the effectiveness of these actions (MacKinley, 1997; Filson, 2004; Sharma & Lacey, 2004; Perez-Rodriguez et al., 2012; Liang and Ge, 2018; Molloy, 2019). It is also interesting if particular strategies or innovations are more effective in earlier stages of firm's development or later.

Start-up firms use number of strategies to increase firm value. Biotech firms pursue expensive R&D projects to develop profitable products which involve long process of scientific discovery, patenting and FDA approval process which may take decades. Capital they raised initially may run out early and firm's survival will require new rounds of financing. According to economic theory, rational value of the firm is determined by present value of future profits and the strategies that increase a likelihood of higher profits should increase firm's market value. This paper creates innovation and strategy categories based on the above expectation of financial market behavior and develops several hypotheses for empirical testing.

Few empirical studies that exist on biotech companies, provide somewhat mixed results between innovation news and stock returns, but most of them focus on large firms. FDA approvals and good scientific news events had positive abnormal returns, while negative news had opposite effect and only small fraction of FDA approvals were associated with abnormal returns (Perez-Rodriguez et al., 2012). Overreaction hypothesis on biotech news events has also been tested and rejected (Peres-Rodriguez et al., 2012), while the study included only large global pharmaceutical firms. The negative news impact based on the Tylenol incident and subsequent regulations of over-the-counter pharmaceuticals on stock prices in that industry has been substantial according to Dowdell et al., (1992). Ahmed (2007) also conducted the study on large pharmaceutical companies and did not find consistent abnormal returns around the dates of new drug approvals by FDA. It could be that FDA approvals were already

expected and priced by investors, based on the previously announced results of clinical trials. Being a leader in the innovation race has substantial advantages, while it has adverse effects on firm values of rivals (Campart and Pfister, 2014). Most of the studies above focused on large scale firms in the industry. Small firms are understudied in biotech. Thus, we decided to document innovation and stock return links for small capitalization firms.

This paper develops broader set of testable hypotheses for startup biotech firms than it has been done previously for this industry, and then conducts empirical testing using event study methodology. The list of scientific innovation and business strategies includes 7 categories: 1) R&D progress and new cooperative research with other entities and scientific community; 2) Obtaining regulatory approvals in the U.S. and abroad; 3) Recruitment of management and consultants with valuable expertise; 4) Pursuing licensing and manufacturing contracts in the U.S. and abroad; 5) Excess to larger stock markets; 6) Conducting new stock offerings; 7) Rebuttal of negative news comments on its stock.

Empirical results show that focusing on regulatory approval of their products; recruiting individuals and consulting firms with valuable specialized expertise in the field; and pursuing licensing and manufacturing deals increased firm value. On the other hand, R&D collaboration and scientific community interaction announcements had mixed effects.

2. Scientific Innovation and Business Strategies Used in Startup Biotech Firms

2.1 R&D Progress and New Cooperative Research with Other Entities and scientific Community

R&D progress and discovery of new benefits of a product brings closer the timeline of the potential revenues and profits, which according to the time value of the money should increase the present value of the project and firm's stock.

Hypothesis 1: Scientific support of potential benefits claimed by the firm' product increases value of its product, firm's profits and its stock value.

2.2 Regulatory Approval Progress in US and Abroad

If firm's product requires lengthy regulatory approval, longer the approval time takes less is the present value of the firm. Positive news on each approval step validates benefit claims of a product and brings the revenue and profit timeline closer.

Hypothesis 2: Regulatory approval progress increases the likelihood of product success, potential revenues and profits and increases value of the firm.

2.3 Recruitment of Management and Consultants with Valuable Expertise

In biotech industry like in most other industries specialized knowledge in field, start-up management, FDA approval process expertise is believed to play a key role in getting the new products to the market. Higher expertise shortens the time it takes for a firm to realize revenues and profits.

Hypothesis 3: Specialized knowledge addition to the firm increases the value of the firm.

2.4 Pursuing Licensing and Manufacturing Contracts in US and Abroad

Licensing and manufacturing contracts prove the value of the firm's technology and bring revenue.

Hypothesis 4: Licensing and manufacturing contracts increase value of the firm.

2.5 Excess to Larger Stock Markets

Increased excess to larger capital markets may reduce cost of capital in case the firm needs to raise new capital.

Hypothesis 5: Excess to larger stock markets increases value of the firm.

2.6 Conducting New Stock Offerings

Successful new stock offering validates investors believe in firm's viability and capacity to pursue and develop new products, which may bring more profits.

Hypothesis 6: New stock issues increase the value of the firm since it increases its capacity to survive and pursue viable projects**.**

2.7 Rebuttal of Negative News Comments About Its Stock

According to economic theory unless there is a fundamental change in company's profit performance stock value will not change. Rebuttal talk without news that might affect profits will not matter for investors.

Hypothesis 7: Providing firm's own opinion on third party reported negative news should have no effect on its stock value.

3. Empirical Methodology

This paper follows the event study methodology used by Filson (2004) and MacKinley (1997). Linear regression specification includes market index and news event dummies in a following manner:

$$R_{it} = \alpha + \beta R_{mt} + \Sigma \gamma_j d_j + \varepsilon_t \quad (1)$$

where R_{it} is firm's daily stock return on day t, R_{mt} is market return (S&P500) on day t,

j is the number of events for firm i, d_j is a dummy variable which takes value of one during the event j event window (event window includes 2 days before the event and one day after the event), α, β and γ_j are estimated coefficients, and ε_t is the error term on date t. Later, Cumulative Abnormal Return (CAR) of the event is calculated by multiplying γ_j on the length of the event window, which is 4 days. T statistic value of event j is same as t statistic of γ_j. Overlapping events are treated as following: they are ranked by importance and only highest-ranking event is included with the note. This estimation method eliminates double counting of abnormal returns on overlapping events.

For this exploratory study on small firms, we selected three small capitalization biotech firms from an alphabetical list of firms. The firm names are: Biotime, BioCryst and Biacore. Following data was collected from various sources: firm's press releases from Lexis-Nexis (188 events total); share prices of each firm from CRSP database, Pennsylvania University, and S&P500 index from Yahoo!Finance. Daily stock price changes and number of shares outstanding are used to create daily return on firm's value. The relevant press releases (events) are categorized in the strategy categories. All press releases are used to create events, except financial announcements. Table 1 provides summary statistics on stock returns of the firms and news events. The firms have a 4-5.9% daily standard deviation of returns compared to S&P500 index's 1%, very typical to startup biotech firms. Later, Wald test is used to test joint significance of events in each category and are reported in Table 3. In Tables 4-6, we also calculate dollar value impact of each significant event by multiplying the event CAR on market capitalization of the firm (stock price times shares outstanding).

Table 1. Summary Statistics

Firms and S&P500	Biotime	BioCryst	Biacore	S&P500
IPO Date	03/05/1992	03/04/1994	11/29/1996	-
Value on IPO date ($)	20,294,000	47,638,500	27,122,380	-
Last Observation	12/31/2003	12/31/2003	12/31/2003	12/31/2003
Number of Observations	2981	2475	1782	2981
Standard Deviation of Returns (Daily)	0.059	0.051	0.040	0.011
Max One Day Return	0.959	0.395	0.876	0.057
Min One Day Return	-0.243	-0.583	-0.881	-0.069
Mean Return (Daily)	0.002	0.002	0.001	0.000
Number of Events	86	64	38	-
Number of Significant Events	10	11	7	-
Ratio of significant events/number of events	0.12	0.17	0.18	-

It is important to note that biotech industry is very large and offers various types of products and services. The firms under the study are not direct competitors. Their business profile differences should be known by analysts and investors following these companies, and it is an open question whether investors react similarly on a same type of

news from the firms operating in different segments of the industry. Our hypothesis tests will provide some evidence on this question, but more extensive research would be needed to answer it.

3.1 Briefly About the Firms

Biotime, Inc. is a biotechnology firm based in Berkeley, California. It develops and markets synthetic plasma and low temperature blood substitute solutions and the technology which is used in surgeries, trauma treatment and preservation of organs awaiting transplant. The U.S. army is also using Biotimes products for its emergency trauma applications. It owns several patents and licenses technology in the U.S., Canada, Europe and Asia. The company went public on March 5, 1992. To sell its products it is required to obtain approvals in each market's regulatory authority such as FDA in the U.S. Table 1 shows summary statistics of its daily stock returns. The company is listed on AMEX.

BioCryst Pharmaceuticals, Inc. was founded in 1986 is based in Birmingham, Alabama. It went public on March 4, 1996. BioCryst develops and markets small-molecular pharmaceuticals for autoimmune and cardiovascular disorders and infectious diseases. It licenses its technology, has patents and FDA approvals on some drugs. Table 1 summarizes performance of its stock returns.

Biacore International is a biotechnology firm based in Upsala, Sweden. It was spun off of Pharmacia & Upjohn, Inc. on Nov 7, 1996 and had an IPO on Nov 29, 1996. Biacore develops and markets effinity-based biosensor technology to medical and life science research laboratories. Its instruments and sensors help during the process of new drug discovery. They also pursue food analysis area. Its stock is listed in Nasdaq and Stockholm Exchange. Table 1 shows its capitalization and stock returns summery statistics.

4. Empirical Results

The regression results of the empirical model show that market coefficients are low (0.43-0.62), thus these stocks are only moderately influenced by market index fluctuations. Our main results are presented in Table 3, where we can examine results for each strategy category. Four categories had statistically significant effects: R&D and scientific announcements; Regulatory approval progress; Recruitment of management and consultants; and Licensing and manufacturing deals. Tables 4-6 present details of each significant event and its dollar value impact on firm's value.

Table 2. Regression Results

Description of Result	Values
Biotime	
Constant term	0.00127
(standard error)	(0.0011)
Beta of Market Factor	0.62
(standard error)	(0.10)
R-Squared	0.05
Adjusted R-squared	0.02
Number of Observations	2981
BioCryst	
Constant term	0.00224
(standard error)	(0.0011)
Beta of Market Factor	0.58
(standard error)	(0.095)
R-Squared	0.097
Adjusted R-squared	0.073
Number of Observations	2475

Biacore	
Constant term	-0.00084
(standard error)	(0.0012)
Beta of Market Factor	0.437
(standard error)	(0.091)
R-Squared	0.089
Adjusted R-squared	0.069
Number of Observations	1782

Notes: Based on daily return data.

Table 3. Cumulative Abnormal Returns for Each Strategy

Event categories	**Biotime**	**BioCryst**	**Biacore**
1. All R&D and Scientific Announcements	-1.84***	-2.57***	1.59***
	(29, 7.33)	(22, 24.64)	(22, 11.11)
Early Period	-0.74	-1.94***	1.24***
	(15, 2.39	(11, 25.99)	(11, 1392)
Later Period	-1.10**	-0.64*	0.35
	(14, 5.36)	(11, 3.37)	(11, 1.096)
2. All Regulatory Approval Process News	1.27***	0.22	N/A
	(15, 7.99)	(10, 0.39)	
Early Period	0.67**	0.35	N/A
	(8, 4.05)	(5, 1.93)	
Later Period	0.60**	-0.13	N/A
	(7, 4.04)	(5, 0.29)	
3. Recruitment of Management or Consultants	1.09***	0.64	0.13
	(10, 9.00)	(13, 2.34)	(2, 0.91)
4. Licensing, manufacturing or new sales reporting	-0.02	0.61*	1.84***
	(12, 0.002)	(9, 3.34)	(12, 29.04)
5. Stock exchange listing changes	-0.20	N/A	N/A
	(3, 0.94)		
6. New stock issues or financing deals	0.06	-0.10	N/A
	(13, 0.019)	(13, 0.09)	
7. Rebuttal on negative news about company or its stock value	-0.14	N/A	N/A
	(3, 0.42)		

Notes: These are the descriptions of the values reported above:

Cumulative Abnormal Returns

(Number of Events, Wald Test Statistic for Significance of Cumulative Abnormal Returns (1 degree of freedom))

Cumulative Abnormal Returns is Σ *CARJ*, where *j* is an event and *J* is the set of events being considered

* significant at the 10% level, ** significant at the 5% level, *** significant at the 1% level

Table 4. Biotime's Significant Events

Date	Event Description	Event Category	CARs	t-value	Impact Value, $
1-Dec-94	McGaw will manufacture BioTime's Hextend for clinical trials	4	0.27 **	2.28	1,578,237
14-Sep-95	Greenbelt Corp. to Serve as BioTime's Financial Adviser	3	0.46 ***	3.99	5,199,695
2-Apr-96	BioTime to optimize Hextend clinical trial protocol	2	0.25 **	2.19	6,100,799
1-Oct-97	Pivotal Phase III Clinical Trial Surgeries Completed in BioTime's Hextend Study; BioTime Shares to Split Three For One	2	0.33 ***	2.87	60,871,590
11-Feb-98	Milton Dresner Joins BioTime Board	3	0.23 *	1.95	32,836,435
15-Jun-98	BioTime's PentaLyte Significantly Reduces Hypovolemic Injury	1	-0.26 **	-2.20	(15,106,807)
5-Nov-99	BioTime Files for Canadian Regulatory Approval of Hextend	2	0.45 ***	3.76	55,629,348
10-Nov-99	BioTime Endows Study of Aging and Low Temperature Medicine At UC Berkeley and the Lawrence Berkeley National Laboratory	1	-0.21 *	-1.78	(24,817,151)
20-Nov-00	BioTime Says New Options Improve Operating Room Safety and the Quality of Recovery	1	-0.29 **	-2.48	(12,175,093)
1-Oct-01	BioTime's Research to be Presented at Berkeley Conference on Aging; BIOWIRE2K	1	-0.21 *	-1.84	(14,127,045)

* significant at the 10% level, ** significant at the 5% level, *** significant at the 1% level

Table 5. BioCryst's Significant Events

Date	Event Description	Event Category	CARs	t-value	Impact Value, $
22-Sep-94	BioCryst Pharmaceuticals adds vice president of medical affairs	3	0.18 *	1.66	7,787,945
31-May-95	Preliminary Results of Extended Open-Label Study Indicate BioCryst's Lead Compound Effective in Treating CTCL; Phase III Clinical Studies to Commence Early Summer	2	0.27 **	2.46	17,311,365
19-Jun-95	BioCryst Corrects Results from Phase II CTCL and Psoriasis Trials	2	-0.24 **	-2.27	(16,948,099)
26-Jun-95	BioCryst Elects William W. Featheringill & Joseph H. Sherrill, Jr. To Board	3	0.18 *	1.68	13,088,542

26-Sep-97	BioCryst Pharmaceuticals, Inc. Announces Preliminary Phase III Trial Data for a Topical Cream Formulation of Lead Drug Candidate, BCX-34	1	-0.40 ***	-3.69	(34,246,202)
24-Aug-99	BioCryst Pharmaceuticals Announces Preliminary Phase II Results From Worldwide Influenza Collaboration With Johnson & Johnson	4	0.28 ***	2.62	135,521,048
8-Feb-00	BioCryst to Receive $4 Million Milestone Payment in Connection With Initiation of Phase III Studies of Oral Neuraminidase Inhibitor RWJ-270201 (BCX-1812) in North America and Europe	4	0.26 **	2.42	113,430,723
12-Oct-00	BioCryst Pharmaceuticals, Inc. Provides Update On Oral Influenza Neuraminidase Inhibitor Program with The R.W. Johnson Pharmaceutical Research Institute	1	-0.77 ***	-7.13	(96,830,297)
22-Dec-00	R.W. Johnson Pharmaceutical Research Institute Updates BioCryst Pharmaceuticals, Inc. on the Status of the RWJ-270201 Clinical Trials	1	-0.51 ***	-4.70	(57,711,828)
3-Jan-02	BioCryst Resumes Phase III Clinical Trial of Peramivir, RWJ-270201, in Influenza	1	0.24 **	2.25	21,129,640
25-Jun-02	BioCryst Pharmaceuticals, Inc. Announces Preliminary Phase III Trial Results for Influenza Neuraminidase Inhibitor, Peramivir	1	-0.89 ***	-8.22	(14,210,787)

* significant at the 10% level, ** significant at the 5% level, *** significant at the 1% level

Table 6. Biacore's Significant Events

Date	Event Description	Event Category	CARs	t-value	Impact Value, $
12-Jan-00	Biacore Targets Major Growth in Drug Discovery Technical Breakthroughs Provide The Basis For Future Expansion	1	0.33 ***	3.37	5,201,524
22-Feb-00	Biacore Enters Collaboration with SmithKline Beecham; Further Deal Validates the Value of Biacore's Technology to the Drug Discovery Industry	4	0.42 ***	4.23	17,555,772
30-May-00	Biacore Establishes a New Pharmaceutical & Biotechnology Industry Business Unit; New Unit to be Located in Switzerland, at the Centre Of Europe's Pharmaceutical Industry	1	0.23 **	2.34	1,287,072
14-Aug-00	Biacore Establishes New Technology Supply Division	4	-0.19 *	-1.92	(1,100,537)
18-Sep-01	New High-Performance System for Quality Control Applications Reduces Time for Assay Development and Validation; Biacore Launches Its First Analytical SPR-Based System for Quality Control Applications in the Regulated Pharmaceutical and Biotechnology Sector	1	-0.22 **	-2.20	(716,097)
28-Sep-01	Acquires An Exclusive License to Axiom Biotechnologies' Cell-Based Platform Technology	4	0.89 ***	8.73	6,609,437
1-Apr-03	New Biacore(R) 3000 GxP Package Launched	1	0.26 ***	2.59	2,553,016

* significant at the 10% level, ** significant at the 5% level, *** significant at the 1% level

4.1 R&D and Scientific Announcements

The results in Table 3-6 show mixed results in support of Hypothesis 1. The R&D related announcements had negative effects on Biotime and BioCryst and positive effect on Biacore. Wald tests on all R&D events were significant at 1% level for all 3 firms. Announcements early on had bigger impact than later announcements in cases of BioCryst and Biacore, but it was other way around for Biotime. These mixed results could be explained by imperfect categorization of events. We suspect that if researched in more detail some events that fall in R&D category for Biacore might belong to regulatory news category where the effects were positive for Biotime and BioCryst. Question is: why R&D and Scientific announcements had negative effect on Biotime and BioCryst? One possible explanation we can offer is that market investors think that if this is the only kind of news out of the

company that means the firm has no better news to report. The better news types could be as it is reported in 4.2, and 4.3.

4.2 Regulatory Approval Progress in US and Abroad

The results strongly support Hypothesis 2 (Table 4-6). Regulatory approval progress news category had positive effect on Biotime's and BioCryst's stocks. The category was significant at 1% level according to Wald test only in case of Biotime and its cumulative CARs was 1.27. Biotimes early news and later news had almost the same effect - CARs were respectively 0.67 and 0.60. This supports the idea that market perceives this type of news positively. This is contrary to findings of Ahmed (2007) and similar to Perez-Rodriguez and Valcarcel (2012). They studied largest firms, where each drug innovation may be a smaller fraction of the firm value.

4.3 Recruitment of Management and Consultants with Valuable Expertise

Hypothesis 3 is supported by the results in this category. The category was significant at 1% level for Biotime only (Table 3) and had positive effect on all three firms' stock values. Second highest event CAR out of all significant events of three firms was in this category for Biotime on Sep 14, 1995 and it was 0.46 (Table 4). Most recruitment events were with positive CARs for all three firms. Two of them had significant events and they were all with positive CARs.

4.4 Pursuing Licensing and Manufacturing Contracts in the U.S. and Abroad

This category has positive effect and is significant at 1% level for Biacore and 10% level for BioCryst and supports Hypothesis 4. Each firm had at least one such positive significant event. Most licensing events had positive CARs. All significant licensing events in all three firms had positive CARs except one event.

4.5 Excess to Larger Stock Markets

Only Biotime had 3 such events and no significance was reported in category or by events. Biotime's cumulative CAR in this category was negative (-0.20). Therefore, the results don't support Hypothesis 5.

4.6 Conducting New Stock Offerings

The results don't support Hypothesis 6. Table 3 shows no significance in this category. Biotime’s category CAR is positive 0.06, but BioCryst’s category CAR is negative -0.10. So results are weak in this category.

4.7 Rebuttal on Negative News Comments on Its Stock

Table 3 results don’t support Hypothesis 7. Only Biotime had such events and Table 2 shows that category is not significant. Although statistically insignificant all event CARs and category CAR are negative.

5. Conclusion

The paper estimates the effect of small biotechnology firms' innovation and business strategies on their stock values. These are some of the conclusions supported by empirical results: (i) firms should focus on regulatory approval of their products; (ii) it is important to recruit individuals and consulting firms with valuable specialized expertise in field; (iii) firms should pursue licensing and manufacturing deals aggressively; and (iv) firms should be highly selective and careful with deals they make for R&D collaboration with scientific community. These implications could be valuable to managers of startup firms in this particular industry and possibly in others, as well as for understanding how financial markets react to innovation announcements. While we find several statistically significant results, multiple studies are needed to retest the hypotheses on other sets of companies, industries and time periods.

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