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VALUATION OF BIOTECHNOLOGY COMPANIES: REAL OPTIONS APPROACH UNDER UNCERTAINTY[1]

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Summary

Biotechnology is one of the most intensive industries in the past few decades. Essence of their operations leads to problem of determining the value of biotechnology companies, because in addition to their existing value, future product, market opportunities and intangible assets are difficult to value. Biotech companies don't have a standard format, and simple techniques, such as financial statements analysis or discounted cash flows cannot be applied. Due to the complexity of their work and high levels of risk, alternative method such as real options is applied. The concept of financial options can be extended to the valuation of investment opportunities in commercial companies, especially in biotech. This paper explains how real options provide various perspectives on the project (investment) value in relation to situations in which the project is: delayed, expanded, abandoned, business is contracted, operations are switched, products with multiple applications are grown, and optimal date for the product launch is determined.

Key words: *Risk, Real options, Valuation, Biotechnology*

JEL: *D04, D81, L65*

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Introduction

Biotechnology as a science has a long tradition and numerous definitions, but the term biotechnology was first used by Hungarian engineer Karl Ereky 1919. Modern biotechnology is defined[3] as a set of techniques used to organically transform particular biological substance[4]. Regardless of many different definitions, biotechnology is perhaps the fastest growing industry in the 21st century, and it is not surprising that it is called the "*new industrial revolution*". Previous experience of developed countries shows that biotechnology will become a key determinant of agricultural development strategy. Expectations are high and it is considered that biotech industry will reduce cost of food production and significantly increase income from agriculture[5].

According to the latest report from Ernst & Young[6], revenues, investment in research and development, net income and number of employees are constantly increasing in recent years. It is consider that US based companies are pioneer of biotechnology industry, but nowadays these technologies have spread around the world, from Europe to China, India and Canada. Biotechnology growth is illustrated in data obtained from BIO (Biotechnology Industry Organization), and according to them the market capitalization of the biotech industry in the 1994-2006 has increased more than nine times[7]. If compared to other industries, except financial, this is an extraordinary growth. However, it is necessary to make a difference, because financial industry was hit hard by financial crisis, while biotech companies grew and developed during the 2009-2010 crisis period. Although this growth was intense, it didn't bring any significant consequences until recently. Reports on strategic business risks[8], however showed that the risks biotechnology companies are facing is growing. The level of risk is somewhat reduced by the current financial crisis, because it affected other industries. Nevertheless the very nature of the business makes risks in biotechnology industry very important.

3 For details on different definitions of biotechnology see Keegan, K. (2008). *Biotechnology Valuation* (ISBN 978-0-470-51178-7). John Wiley & Sons Ltd, Chichester and Montague, P. (1993). Biotechnology Patents and the Problem of Obviousness. *Australian Intellectual Property Journal,* The Law Book Company Limited, 4(1), pp. 1-31, Pyrmont.

4 Jovanović, S., Reljić, M., Sikora, S. (2011): Zaštita intelektualne svojine u biotehnologiji. *Industrija*, Ekonomski institute, 39(4), p. 210, Beograd.

5 Vićentijević, D., Aćimović, L., Stevanović, S. (2011): *Uticaj tehnološkog razvoja na održivi razvoj poljoprivrede i zaštitu životne sredine*, Ekonomika poljoprivrede, Naučno društvo agrarnih ekonomista Balkana, Beograd, Institut za ekonomiku poljoprivrede, Beograd, Akademija ekonomskih nauka, Bukurešt, 58(2), p. 198, Beograd.

6 Ernst & Young (2011): Beyond borders Global biotechnology report 2011, p.37.

7 Biotechnology Industry Organization (BIO) (2008): The Guide to Biotechnology 2008, p. 3.

8 For details see Strategic Business Report Ernst&Young, 2008, 2009, 2010, available from Company's web page.

On the other hand Papić-Brankov and Lovre[9] argue that current financial crisis reduced level of investments in biotech industry, as investors seek risk-free investment. As a consequence of this trend number of biotechnology companies declined, capital structure concentrated and monopoly position of multinational companies in the field of biotechnology has strengthened.

Valuation of biotechnology companies

Valuation has its theoretical basis in the economic theory of investment choice, which is on the other hand based on the investments profitability, *i.e.*, the evaluation process is focused on valuation of interest[10]. Because of the specificity of biotech companies, their value is defined as the sum of existing values, market opportunities and future products. Therefore, when valuating biotechnology companies, it is necessary to add value of all future products that are developed today. However, the problem is how to valuate existing opportunities, when they are not real products, but only chances that can become a usable product in the future, and on that basis make profit.

In order to understand valuation process, it is necessary to explain how new drugs (product) are developed in biotech companies. This process is by its nature very risky, expensive and long. Drug development process consists of several different phases, which can be summarized in two basic: research and development phase and commercialization. This paper shows only the basis of each phase, which will later serve in order to clarify biotech companies valuation[11]. The first phase is discovery, which is concept creation of new findings, based on the idea or hypothesis. This phase is followed by pre-clinical trials that can last from 3 to 6 years. If the first and the second phases are successful and all the necessary permits from the authorities are obtained, creating a drug enters the third phase, the phase of clinical trials, when product is tested on humans. The third stage can be divided into three parts or periods. In the first period tests are performed only on a small number of subjects and this phase can last from 6 months to a year. The second period involves use of the drug on a larger number of users who are in need of that particular product, and lasts just as long as the first period of this phase. In the third period that may last from 1 to 4 years a group of people to which the product is tested expands, and this phase is supposed to replicate market behavior of the drug. If all previous phases are successfully completed, a request for approval is submitted to regulatory authorities. The final stage involves the

9 Papić-Brankov, T., Lovre, K. (2010): *Implikacije svetske ekonomske krize na biotehnološku industriju*, Ekonomika poljoprivrede, Naučno društvo agrarnih ekonomista Balkana, Beograd, Institut za ekonomiku poljoprivrede, Beograd, Akademija ekonomskih nauka, Bukurešt, 57(3), p. 374, Beograd.

10 Pavlović, V., Knežević, G. (2008): Adekvatnost tržišne metode procene kapitala za potrebe privatizacije. *Računovodstvo*, Računovodstvo D.O.O. i Savez računovođa i revizora Srbije, 52(5-6), p. 110, Beograd.

11 For details on drug development process see Kellog, D., Charnes, J. (2000): Real options valuation for a biotechnology company. *Financial Analysis Journal*, CFA Institute, 56(3), pp. 76-84, Charlottesville.

post approval, and includes post-marketing surveillance.When a product is already on the market and it can reap revenue, companies often invest more in marketing so they could boost sales of that specific products. Most authors agrees that it takes around 15 years in order to complete this process, while one of the world's largest commercial biotechnology company concludes that this process has recently accelerated, and is on average 12 years. It is considered that department of research and development is responsible for success of the particular product. As investment in research and development increases, the chances of drug success are bigger.

Valuation of intangible assets in biotech companies

Intangible assets are fixed assets that don't have material (physical) form. These types of asset don't have a clearly defined, realistic marketable value as other forms of property, so its value is determined on the basis of future assessment its impact on profit increasing. Kruger[12] believes that organizations that successfully identify new opportunities have immaterial or cognitive infrastructure that allows them to see opportunities and to respond to them. Intangible assets have four basic characteristics that we must take into account when choosing method for valuating biotech companies. These assets can be used repeatedly at the same time and are not subject to the law of diminishing returns. Furthermore, intangible assets have a strong impact on the overall business. The most important characteristic is that intangible assets are oriented towards the future, and they increase future value of the company. According to Jovanovic et al.[13] intangible assets participation in business activities is constantly growing. From 5% in the late 1970s, this share increased to 90% in 2004.

Probabilistic approach to the evaluation

If the company has a standard format, one can apply simple valuation techniques, such as financial statement analysis or discounted cash flows[14]. These methods are usually used to valuate companies that are in the mature stage of life cycle, don't have a lot of intangible assets, and cash flows and earnings can be easily measured. As biotech companies can't be categorized this way, these methods will not be addressed in this paper. Keegan[15] concludes

12 Krueger, N. (2000): The cognitive infrastructure of opportunity emergence. *Entrepreneurship Theory and Practice*, The United States Association for Small Business and Entrepreneurship, Spring issue, p. 6, Nashville.

13 Jovanović, S., Matović, D., Petrović, S (2011). Vrednovanje intelektualne svojine. *Industrija*, Ekonomski institut, 39(2), p. 96, Beograd.

14 For details about the shortcomings of discounted cash flow techniques seen in Rađenović, T. (2008). Real options. *Facta universitatis – series: Economics and Organization*, University of Niš, 5(1),pp. 89-92, Niš.

15 Keegan, K. (2008). *Biotechnology Valuation* (ISBN 978-0-470-51178-7). John Wiley & Sons Ltd, Chichester, p. 128.

that there are a growing number of studies that criticize the use of traditional technique for valuation of biotechnology companies. Namely, it is considered the traditional approach precludes future opportunities for growth, and potential value for shareholders. In biotechnology and other research intense industries, value in the product development process can occur long before going to market.

Real options

Different types of options have always been used in commerce and trade. Romans and Phoenicians practiced a big part of their overseas trade through the options, while in the Netherlands options were used when buying tulip bulb, which subsequently led to the first price bubble in the world history. Financial options give the owner the right but not the obligation, to buy or sell a financial asset at pre-specified exercise price. The buyer (or seller, depending on the type of option) will exercise option only if there is financial benefit. If this doesn't happen, the buyer (or seller) will leave option to expire and it will not be exercised. Analogy between financial options and real investment first noticed Myers back in the 1984[16]. In his work[17] he used for the first time term *real options* suggesting that investment opportunities engaged in the research and development that have a great deal of intangible assets, can be evaluated according to the principle of financial options. These options have the same characteristics as all other financial options, but they are options of growth and development (so they are real), whose value is mostly affected by the strategic management investment decisions. Pakson[18] defined real option as opportunities (or commitments) to acquire or develop or dispose of real assets at a price determined (or estimated) in the present but settled, or delivered, in the future. He also stated that like financial options, there is conceptually an underlying asset, or liability, that determines the option value at expiration, but unlike financial options, real options are not commonly traded, are often difficult to identify, and may involve more complex methods for valuation. Some authors believe that the real options, as techniques for the valuation emerged from decision tree (decision trees are also used as a method for valuation under risk and uncertainty). In biotech real option valuation is equivalent to a series of call options in each of phases of drug development process, mentioned above.

Although real options were identified as an opportunity to valuate companies with a significant part of the intangible assets, more frequent use of these instruments wasn't possible until 1973 when two Nobel laureates Robert Merton and Myron Scholl developed, now legendary model (Black&Scholes) for valuation of options and other derivatives.

16 According to some authors the basics of real options, but not under that name, has set up Jevon in1871in his book Theory of Political Economy, for details see Jevons, W. (1888). *The theory of political economy* (ISBN: 81-224-1278-5). MacMillan and Co, London.

17 For details see Myers, S., (1984). Financial theory and financial strategy. *Interfaces,* Informs 14, pp. 126–137, Hanover.

18 Paxson, D. (1996). Real options in *The Blackwell Encyclopedic Dictionary of Finance* (ISBN-10: 155786912X). edited by Dean and Douglas Wood, Manchester Business School, p.287.

There are two basic types of options, put and call. Call option gives holder the right to buy the underlying asset at a pre-specified exercise price (or strike price). Thus, the buyer has the right but not the obligation, to buy certain assets. On the other hand, the seller is obliged to sell the same assets at the agreed terms. It is clear that buyer of a call option prefers when price of financial instrument he bought is growing. Seller of a call option, on the other side, gets a premium, but risks losing if the option price rises more than the premium. Put option is an agreement the two sides to exchange the underlying asset at a specified price, the strike, by a predetermined date, the expiry or maturity. There are three main possibilities in which the buyer and seller of call options can be found. The first one is called "*in-the-money*" and involves a situation where the cash flows from options are positive for seller, so the strike price of call (put) option must be lower (higher) than the current market price of basic assets. If the situation is reversed, and if it would provide a negative payoff, the situation is called "*out-of-the-market*". The last option means that exercise and market price are equal and it is said that option is "*at-the-market*". One more distinction is necessary to be mentioned, before we proceed with explaining the valuation process through the real options. There is also difference between American call option that can be it can be exercised anytime from the date of purchase until the expiration date and European call option that can be exercised only on the expiration date. For valuation of European options Black&Scholes model is best option, while American options are usually valuated with use of binomial trees. Black&Scholes model is based on financial call option, which is analogous to investment option in new product development after considering all relevant factors in biotech companies.

Call option price in the Black&Scholes[19] model is calculated as follows:

$$V = SN(d_1) - Ke^{-rt}N(d_2), \text{where:}$$

$$d_1 = \frac{\ln\left(\frac{S}{K}\right) + (r + \frac{\sigma^2}{2})t}{\sigma\sqrt{t}}$$

$$d_2 = d_1 + \sigma\sqrt{t}$$

V = value of an call option
S = current value of the underlying asset
K = strike price of the option
r = risk-free rate corresponding to life of the option
t = life to expiration of the option
σ^2 = variance in the value of the underlying asset

19 Black, F., Scholes, M. (1973). The pricing of options and corporate liabilities. *Journal of Political Economy*, *University of Chicago Press,* 81, p. 637-654, Chicago

The process of options valuation has several steps according to Damodaran[20]. First, the inputs to the Black&Scholes model are used to estimate *d1* and *d2*. Then cumulative normal distribution functions, *N (d1)* and *N (d2)*, corresponding to these standardized normal variables are estimated. After this the present value of the exercise price is estimated, using the continuous time version of the present value formulation Ke^{-rt} Ke^{-rt} Ke^{-rt}. Finally the value of the call is estimated from the Black&Scholes model. Within the model, four parameters, the market price, the exercise price, risk free rate and time to maturity are known variables, or it is easy to calculate them. Variance in the value of the underlying asset is problem that must be estimated in order to valuate future business opportunities.

Real options are suitable for assessment of intangible assets because their value depends mostly on previous decisions and actions of strategic management, and also there is substantial uncertainty or risk related to them. If intangible assets are considered this way valuation can be identified with the valuation of financing options and Black&Schol model can be applied to valuation of intangible assets. Basic assumption would be: A company that has opportunity to invest in intangible assets has the ability but not the obligation to continue investment (or to invest for the first time) in order to ensure future positive cash flows from a specific project. So, now we can draw an analogy to specific Black&Schol model. The current price should be viewed as the present value of the project on which company has the option, the expected price would be the equivalent of project costs (final cost or cost of certain stages, depending on the horizon of observation), time to maturity is the same as time to make an investment decision, and the volatility of asset prices is related to the project uncertainty.

Damodaran[21] in his first paper about the use of real options in valuation states that real options can be used for capital budgeting, or to decide between three alternatives: delay, expand or abandon. Companies that have "luxury" to *delay* their investment usually have a good competitive position in the market or exclusive rights to the certain project. Projects that biotech companies implement have such characteristics, because their products are in essence, a new discovery. On the other hand there is a long horizon for new drug development, so delaying some phase of the project might be useful. The investment decision to be made in this case is equal to call option on that particular project. Strike price is identical to the initial investment and option time to maturity is the same as time that company needed so it can make a decision.

Often investment in project opens the possibility of investing in other (*expand*), which will make profit. If considering phases of drug development process in biotech industry, it is clear that this is a typical example of situation where investments could be expanded. Finalization of each phase opens up opportunities for next subsequent

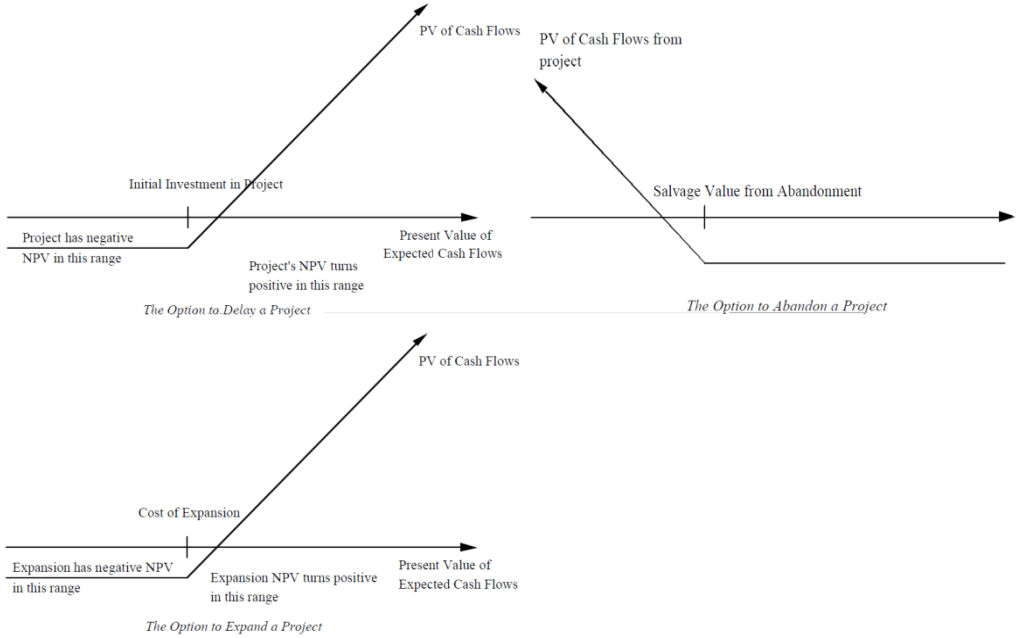
20 Damodaran, A. (2010). T*he Dark Side of Valuation Valuing Young, Distressed, and Complex Businesses* (ISBN-10: 0-13-712689-1). FT Press, New Jersey, p. 140.

21 Damodaran, A. (2001). The promise and peril of real options. Research Paper, Stern School of Business, New York, NY, p.25.

phase, and finally, creates the possibility of product realization and commercialization. Negative cash flows at the beginning of the project, are compensated by high cash flows in the commercialization phase. Valuation of this situation can also be identified with a call option, with exception that the strike price equal to the cost of expansion.

Sometimes it is better to *abandon* the project at earlier stages of development and with lower costs. Costs may pile up and the project could experience failure when entering the market. It is better to stop development of drug (product) in some part of clinical trials than to accumulate costs. This situation can be identified with put option. These three situations are graphically illustrated at following picture.

Picture 1. Illustration of different types of options



Source: Damodaran, A. (2010). The Dark Side of Valuation Valuing Young, Distressed, and Complex Businesses. FT Press, New Jersey.

These three options explained in Damodaran are universal and can be applied to companies in every industry. Keegan[22] adds more types of options that are specific to the biotech industry. The first option would be to *contract* activity, when it is determined that drug asset are deemed less attractive, either due to lack of effectiveness or a diminished commercial opportunity. The next option is an option to *switch* operations that can refer to the cost of restarting activities (for example manufacturing capability). Last option would be *grow* option, or development of products that are reusable and

22 Keegan, K. (2008). *Biotechnology Valuation* (ISBN 978-0-470-51178-7). John Wiley & Sons Ltd, Chichester, p. 129.

have multiple applications. In addition to Keegan Vernimen et al.[23] dealt with this issue and added two more options, option to *launch a new project*, which would be equivalent to a call option on the new investment project. This is especially applicable in the field of biotechnology, since the launch of a new product does not provide cash flows until final commercialization. Another option mentioned by the authors is option to determine *optimal date for starting up a project*. In this case the waiting period is identical to holding American option on the project, and this situation is a similar to an option to abandon project.

Although Keegan[24] believes that options are relatively good technique for the valuation in the field of biotechnology, he also states that they have significant shortcomings. Corporate investment and especially those in biotechnology are more complex than financial options that can be evaluated with Black&Schols model. The assumption about lognormal distributed project values is generally not appropriate, and formula from Black&Schols model is not intuitive. Volatility as an input is difficult to measure in practice. Also, Black&Schols model is suitable only for calculating the value of European options, while the valuation of American options is difficult and in this case some other techniques such as decision trees or Monte Karlo are suitable.

Criticism of real options can be found in Smith and Par[25] who argue that discounted cash flow technique is better, and that real options will always give greater value because they consider only favorable activities. Also they claim that real options are just permutation of basic discounted cash flow technique.

Concluding Remarks

The last two decades of the 20th century are characterized by increasing use of intangible investments around the world, regardless of the industry within which company operates. These intangible assets are manifested in many different forms, such as skills, new organizational structures, know-how, patents, licenses, development of new products and more. Although these changes are felt in all areas of business, the greatest impact is on industries that are research intensive like for instance biotech companies. On the other hand level of risk in the global environment is constantly increasing while in the field of biotechnology it is traditionally dominant (it is considered that the biotechnology industry is the second riskiest, right after the property industry). So it is clear that there has to be done something in order to improve techniques for valuation in conditions of risk and uncertainty.

23 Vernimmen, P., Quiry, P., Dallocchio, M., Le Fur, Z., Salvi, A. (2009). *Corporate Finance Theory and Practice* (ISBN-10: 0470092254). John Wiley & Sons Ltd, Chichester, pp. 374-375.

24 Keegan, K. (2008). *Biotechnology Valuation* (ISBN 978-0-470-51178-7). John Wiley & Sons Ltd, Chichester, p. 128.

25 Smith, G., Parr, R. (2005). *Intellectual Property. Valuation, Exploitation, And Infringement Damages* (ISBN-10: 047168323X). John Wiley and Sons, New Jersey, p. 300.

Techniques such as simple discounted cash flow analysis are long outdated, and new methods that are created tend to involve a risk to existing models. This is the reason why improvement such as real option analysis, decision trees, scenario analysis, simulation and Monte Carlo models are introduced in order to improve discounted cash flow and other simple methods. It is shown more than once that the concept of financial options can be extended to the assessment of investment opportunities, especially in biotechnology. Real options provide a different perspective on the valuation of a project (investment) in situations in which the project is delayed, expanded, abandoned, contracted, switched, has a *grow* option, optimal date for *launching a new project,* or *optimal date for starting up a project is determined*.

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VREDNOVANJE PREDUZEĆA IZ OBLASTI BIOTEHNOLOGIJE: PRISTUP REALNIH OPCIJA U USLOVIMA NEIZVESNOSTI

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Rezime

Biotehnologija je jedna od najintenzivnijih industrija u poslednjih par decenija. Ovaj intenzivni rast došao je sa posledicama koje se prevashodno ogledaju u velikom nivou rizika koji preduzeća preuzimaju pri razvoju novih proizvoda. Zbog specifičnosti posla kojima se preduzeća iz oblasti biotehnologije bave, javlja se problem vrednovanja, jer se osim postojećih vrednosti, budući proizvodi, tržišne šanse i nematerijalna ulaganja teško valorizuju. Biotehnološka preduzeća nemaju standardni format, te se jednostavne tehnike, kao što je analiza finansijskih izveštaja ili diskontovanje novčanih tokova ne mogu primeniti. Usled kompleksnosti posla i visokog rizika primenjuju se alternativne metode kao što su realne opcije, koje su u ovom radu detaljno objašnjene, ali i stabla odlučivanja, scenario analiza, simulacije, Monte Karlo modeli, i ostalo. Koncept finansijskih opcija se može proširiti i na vrednovanje investicionih prilika u poslovnim preduzećima, a posebno u biotehnolgiji. Imajući ovo u vidu u ovom radu je objašnjeno kako realne opcije pružaju različite perspektive sagledavanja vrednosti projekta (investicije) u odnosu na situacije u kojima je projekat odložen, proširen, napušten, kontrakovana je delatnost, promenjene su mu operacije, razvijen je proizvod sa više namena, određen je optimalan datum za lansiranje proizvoda.

Ključne reči: *rizik, realne opcije, vrednovanje, biotehnologija*

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