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COMMENTARY

Stem cell industry update: 2012 to 2016 reveals accelerated investment, but market capitalization and earnings lag

MITCHELL NG[1,*], SIMON SONG[2,*], NICOLAS S. PIUZZI[1,3], KENNETH NG[4], CHUKWUWEIKE GWAM[5], MICHAEL A. MONT[1] & GEORGE F. MUSCHLER[1]

[1]Cleveland Clinic, Department of Orthopedic Surgery, Cleveland, Ohio, USA, [2]Duke University, Department of Biomedical Engineering, Durham, North Carolina, USA, [3]Instituto Universitario del Hospital Italiano de Buenos Aires, Buenos Aires, Argentina, [4]State University of New York Downstate Medical Center, College of Medicine, Brooklyn, New York, USA, and [5]Rubin Institute for Advanced Orthopedics, Center for Joint Preservation and Replacement, Sinai Hospital of Baltimore, Baltimore, Maryland, USA

Abstract

Treatments based on stem cells have long been heralded for their potential to drive the future of regenerative medicine and have inspired increasing medical and business interest. The stem cell therapy market has been expanding since 2012, but earnings and profitability still lag the broader health care sector (compounded annual growth rate in annual financing of 31.5% versus 13.4%, respectively). On the basis of historical financial data, approximately $23 billion has been invested in stem cell companies since 1994, with more than 80% of this raised from 2011 through 2016. This reflects a marked acceleration in capital investment, as companies began late-stage clinical trials, initiate partnerships or are acquired by large pharmaceutical companies. All of these data reflect a field that is emerging from infancy, which will demand more time and capital to mature. This update is relevant to researchers, clinicians and investors who wish to quantify the potential in this field.

Key Words: *cellular therapy, market analysis, stem cell market*

Introduction

Interest in regenerative medicine continues to increase, particularly, work focused on developing cell-based therapies to repair or regenerate damaged tissue [1]. There appears to be growing optimism that stem cell–based therapies may revolutionize disease treatment [2]. This confidence may be enhanced by promising findings made in the research field that were disseminated to the public without acknowledgment of the persisting obstacles and challenges [2]. Cell therapies in various forms are being marketed widely and sold as treatments, sometimes without evidence of clinical efficacy from clinical trials and narrowly skirting regulatory guidelines that can variably seem vague, arbitrary, negotiable, biologically capricious or unenforceable [3]. Although there is evidence that support many clinical application of stem cell therapies, major hurdles remain in translating basic science discoveries into safe, clinically proven and rationally regulated treatment modalities.

We are in the early phase of clinical development in the stem cell field. Biotechnology companies are grounded in stem cell biology but become responsible for translating basic stem cell biology into reliable products. This includes the substantial fundraising that is needed to gather evidence of clinical safety and efficacy through clinical trials. The valuation of these companies is largely based on the strength of their intellectual property position, the clarity of their regulatory path, the size of the market they may serve and therapeutic promise or magnitude of impact their product might achieve.

Previous studies of the stem cell market place have been directed toward characterizing size and growth [4–6]. The market for stem cell therapies was valued

*These authors contributed equally to this work.
Correspondence: **George F. Muschler**, MD, Department of Orthopaedic Surgery and Biomedical Engineering, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195, USA. E-mail: muschlg@ccf.org

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at $2.7 billion in 2010 with the majority of revenue coming from bone marrow–derived products [7]. A market analysis of Q4 2012 and Q1 2013 revealed strong progress in commercialization and translation of cell therapy companies, indicated by a calculated cell therapy index (CTI) of companies with market capitalizations greater than $50 million [8]. A separate study reported data through mid-2011 indicating a tissue engineering and stem cell industry expenditure of $3.6 billion, with orthopedics comprising the largest individual share at 49% or $1.7 billion in [6]. Up to this point, the metrics included in these academic studies have been largely limited to comparisons of stem cell companies by market capitalization, revenue and projected growth. To the best of our knowledge, however, there have been no analyses of the underlying financial metrics responsible for these overall numbers (e.g., price-to-earnings ratio, earnings before interest/taxes/depreciation/amortization aka EBITDA, and capital raise breakdown).

Therefore, this study comprehensively analyzed the stem cell market from a financial perspective. Our primary aims were to (i) provide a 2012–2016 update of the stem cell market size and growth using the stem cell therapy index (SCTI); (ii) analyze historical stem cell investment data, including characterization of the quantity and type of investment (e.g., debt/senior notes, convertibles, preferred equity, common stock) into stem cell companies relative to other health care industries (e.g., diagnostics, small molecules, medical devices); and (iii) identify key events and important clinical developments that helped drive this expansion.

Methods

Update of the stem cell market size and growth from 2012 to 2016 by calculation of Stem Cell Therapy Index

The Stem Cell Therapy Index (SCTI) is a 23-company index composed of primarily U.S.-exchange-listed publicly traded companies that have at least one stem cell therapy either currently marketed or in development (inclusion criteria), with a cutoff of a market capitalization of $50 million to ensure a certain level of liquidity (exclusion criteria) (Supplemental Table S1). The remainder of the SCTI inclusion–exclusion criteria are analogous to the CTI, which was constructed to analyze the cell therapy industry's progress in 2012–2013 [8], whereas our constructed SCTI focuses on the stem cell therapy subsector and reflects developments from 2012 to 2016.

Furthermore, financial metrics such as (i) revenue; (ii) EBITDA, a measure of profitability; and (iii) price to earnings ratio (P/E ratio) are also provided for each company as a basic financial summary. All financial information was obtained from publicly accessible sources (Bloomberg, Yahoo Finance, Google Finance) and adhered to industry-standard definitions found in resources such as Investments [9] or Investopedia. Information on the pipeline and product characteristics are from BioCentury IQ (BCIQ) and the websites of individual companies. In line with previous literature [8], and due to a lack of available data, no differentiation was made within companies that added portfolio cell therapy products that are not "stem cells," such as T cells. Instead, we relied out inclusion–exclusion criteria to appropriately define companies for analysis.

To construct the SCTI from January 2, 2012, to December 30, 2016, the daily returns of each company in the index were computed and equally weighed, with the index starting at 1000. For comparison, two well-established biotechnology exchange-traded funds (ETFS), the NYSE Arca Biotechnology Index (INDEXNYSEGIS: BTK) and the NASDAQ Biotechnology Index (INDEXNASDAQ: NBI) were normalized to begin at 1000 and also plotted for the same duration to serve as a baseline comparison for volatility and the effect of macroeconomic trends and healthcare specific catalysts. The NASDAQ and NYSE indices are among biotech's most trusted and were previously used for baseline comparison against the cell therapy index CTI [8].

Initially, there were instances where the stock price of one company would increase by more than 1000% in 1 day; for Vericel Corporation (Ann Arbor, Michigan, USA), on October 16, 2013, the company announced a 1-for-20 reverse stock split. For Capricor Therapeutics (Beverly Hills, California, USA), on November 22, 2013, the company announced the completed merger between Capricor, Inc., and Nile Therapeutics (San Francisco, California, USA). To reflect that the short-term volatility in stock performance was not due to a perceived increase in profitability or value, these outlier daily returns were omitted from the performance of the SCTI.

Financing data on stem cell therapy market and other health care industries

All data were obtained from the BioCentury (BCIQ; https://www.biocentury.com), a database primarily designed for and subscribed by biotechnology/pharmaceutical companies and investors. BCIQ integrates more than 20 years of BioCentury's analysis of public and private companies in the health care space and contains information on drug pipelines and major developments and news, along with fundraising efforts across a variety of asset classes. For this study, a geographic filter was applied so that only companies in the United States were considered, and another filter was applied for therapeutic modality to separate data for

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