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HANA BIOSCIENCES, INC.: A CASE STUDY IN BIOPHARMACEUTICAL ENTREPRENEURSHIP

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ABSTRACT

Hana Biosciences is a South San Francisco-based development stage biopharmaceutical company committed to advancing cancer care. Despite breakthroughs in biological insights in the last twenty-five years, translating scientific progress into increased biopharmaceutical industry productivity has been elusive, as capital costs continue to rise and product development timelines lengthen. On average, it takes over $1.0 billion and 12 years to progress a product candidate from target identification to marketing approval. This case considers decisions faced by a biopharmaceutical start-up as the company works to build its product pipeline and establish commercial capabilities.

THE ROAD TO HANA

Hana Biosciences (NASDAQ: HNAB) is a South San Francisco-based biopharmaceutical company committed to advancing cancer care. It was founded in 2003, nearly three decades after the inception of the biotechnology industry. The name Hana means "health" in Hawaiian, the birthplace of Mark Ahn, founder and CEO of the company. The name also evokes the fabled road to Hana, a 56-mile trip full of sharp twists and turns on the island of Maui. The drive can be nauseating at times, but offers a glimpse of paradise if one can withstand the journey. Early on, the management team often used this "road to Hana" as a metaphor for their biopharmaceutical start-up. In the first three years, the team discovered that they were more correct than they could have ever possibly imagined.

Hana assembled an experienced management team whose members came primarily from large biotechnology and traditional pharmaceutical companies such as Genentech, Amgen, Gilead, and Bristol-Myers Squibb, as well as from academia. Their backgrounds and professional passions were particularly focused on developing and commercializing new drugs for the treatment and supportive care of cancer patients. Most of the team members previously worked on multiple oncology products, including blockbuster drugs with over $1 billion in annual sales, such as Amgen's Epogen, Genentech's Rituxan and Novartis's Gleevac. Prior to starting Hana, many team members had already been based in the South San Francisco area, working at a cluster of biotechnology companies surrounding industry pioneer, Genentech. The Bay area location also made it easier to recruit talent, since Northern California offered the world's largest concentration of biotech companies, as well as leading research institutions such as Stanford, UCSF and UC Berkeley. In addition, proximity to Silicon Valley venture capitalists provided access to the most active group of early stage biotech investors.

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As Hana founders surveyed the operating environment of the biopharmaceutical industry, they sought to take a realistic view of the key trends and orthodoxies that drove the industry. Biotechnology has been an industry built on promise, but the reality has been a few spectacular successes that brought life-saving drugs to patients and outstanding returns to shareholders (i.e., Amgen, Biogen-Idec, Genentech, Genzyme, and Gilead) punctuated by many more wrenching setbacks, with financial losses to match. Despite the collective breadth and backgrounds of team members, Hana's management team faced a number of challenging fundamental questions facing nearly all start-up biopharmaceutical companies: "Does the biotechnology industry need yet another small, pre-revenue, unprofitable company to add to the hundreds of such companies already in existence? What will make Hana Biosciences' value proposition unique and sustainable? Does this team possess the necessary core competencies, technology, and access to capital to build a sustainable company?"

BIOPHARMACEUTICAL INDUSTRY

Since the US FDA approved the first biotechnology drug (recombinant insulin, developed by Genentech and licensed to Eli Lilly and Company) in 1982, the biopharmaceutical industry has had 254 drugs approved for 385 indications with over $40 billion in sales. In addition, over 300 drugs are currently in clinical development targeting over 200 diseases. The industry employs over 200,000 people and spends over $20 billion annually on research and development.[1]

Despite this tremendous investment, productivity over the years has been decreasing, with higher drug development costs and longer clinical development timelines. The average drug takes over $1.0 billion and 12 years to go from laboratory to approval (see Appendix 1). Part of the reason for these large costs is the high failure rate of product candidates in clinical trials. For the drug candidates that progress from animal testing into human clinical trials, the overall success rate is 11%. In other words, nine out of ten products entering clinical trials will fail, and some disease areas are even more challenging (i.e., oncology success rates are approximately 5%). Furthermore, getting approval is no guarantee of commercial success. To date, only 4 out of 10 products that reach the market achieve profitability. This lack of development productivity (either increasing the value created or decreasing the time required to create value) has taken its toll on financial performance of the industry. Out of the nearly 350 publicly traded biopharmaceutical companies, fewer than 10 reached sustainable profitability.[1,2,3,4,5]

Despite the formidable odds in drug development, the excitement surrounding biomedical enterprises remains high. Fundamental forces shaping the biotechnology industry in the first decade of 21st century include: (1) The gap between the low cost of creating a biotech company around an exciting scientific discovery and the extremely high costs of converting novel technologies into approved drugs; (2) Steady evolution of the perception of value by investors in the biopharmaceutical industry value chain; (3) The irregular nature of biotechnology financial markets increases operating risk and uncertainty; and (4) Despite intense competitive pressure, product pipelines remain

highly valued because large multinational pharmaceutical companies increasingly need more products given declining productivity and pernicious attrition rates.

First, a persistent issue is the gap between the low cost of creating a biotech company around an exciting scientific discovery and the extremely high costs of converting novel technologies into approved drugs. Ever-broadening access to molecular biology tools, rapidly growing body of knowledge about basic biological processes, and use of information-based research technologies in academic laboratories and research institutes made it easy to create a new company by spinning the basic technology out of academia. Academic research is more likely to result in breakthrough innovation due to the large numbers of scientists, resources, and patience with the scientific process. While the core competency of academia is basic research (defined as laboratory-based target validation and lead optimization), however, most universities are not resourced to translate discoveries from the lab to clinical studies. This process of translational development from the lab typically includes process development and manufacturing, toxicology testing, regulatory filings with the FDA (US Food and Drug Administration), and mobilizing physician investigators to enroll patients into early stage clinical studies. Fueled by the expanded access to research tools and biological insights from the human genome and by venture capital firms willing to invest in novel science, the excitement of creating new companies has resulted in large numbers of small, undercapitalized startups focused on discovery of novel drug targets but lacking resources needed to convert these targets into drug candidates and to validate them in the clinic.

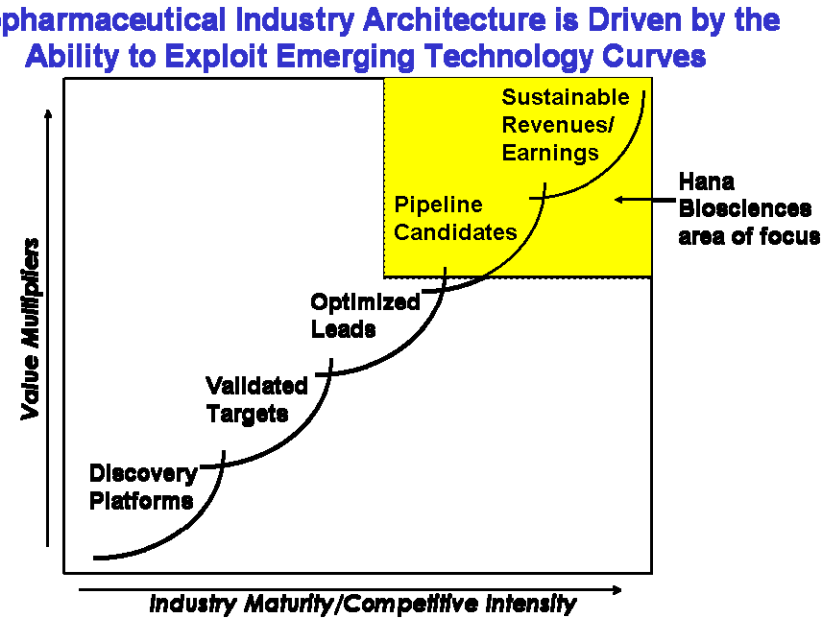
Second, another fundamental factor is the steady evolution of the perception of value by investors in the biopharmaceutical industry value chain. In three decades, biopharmaceutical industry investors went from ascribing value solely to platform technologies to requiring clinical stage product candidates to expecting revenues and finally, to demanding sustainable profitability (see figure 1). That is, as in all other industries based on technological breakthroughs, investors in biopharmaceutical companies increasingly demand commercially realizable opportunities to justify additional capital.[6] In the early 1990s, the highest market valuations went to companies with technology platforms which *may* potentially lead to biologic targets (i.e., Human Genome Sciences, a biotech start-up, granted GlaxoSmithKline, a top 10 pharmaceutical company, access to its gene-based drug technology in a partnership valued at $125 million). Over the next decade, the "sweet spot" of venture capitalists and financial markets steadily migrated through the value chain:

- from valuing novel drug targets (i.e., Bayer, a big pharma company, paid five-year old Millennium Pharmaceuticals over $1.0 billion to deliver 225 drug targets over 5 years);
- to focusing on product leads (i.e., Hoffman-La Roche acquired a 60% stake in Genentech in exchange for right of first refusal to all Genentech products outside the US);
- to acquiring development candidates in clinical trials (i.e., Amgen entered into an alliance with Abgenix to co-development monoclonal antibodies over five years

which led to Vectibix, then subsequently acquired the company for $2.2 billion after positive Phase III clinical trial results to obtain full ownership and eliminate future royalties);
- to paying for revenues from approved products that led to increased merger and acquisition activity, with Pfizer acquiring Agouron, Johnson & Johnson acquiring Centocor, etc.

Further, distinctions between traditional Big Pharma companies and smaller biotechs have increasingly blurred due to alliances and converging research interests. This trend is increasing competitive intensity in the marketplace, as multiple players pursue drugs with the same mechanisms of action in overlapping indications (i.e., multi-kinase inhibitors Sutent by Pfizer and Nexavar by Onyx/Bayer in renal cell cancer; or EGFR inhibitors Tarceva by Genentech/OSI, Erbitux by Bristol-Meyers Squibb/Imclone, and Vectibix by Amgen). The result of increasing competitiveness for the same molecular targets is shorter periods of effective intellectual property exclusivity and profit margin pressure.

Figure 1



Third, the irregular nature of biotechnology financial markets increases operating risk and uncertainty. As a result of large capital requirements, long lead times, and episodic successes and failures, biotech financing cycles have been characterized by periods of high euphoria, only to be followed by deep disillusionment after a cluster of high-profile product failures that seemed to occur regularly.[7] This subjects early-stage companies to high degrees of financing risks, regardless of their operational progress**.** While the industry has matured, the predominant venture capital financing model—one product platform or one product, a few investors who provide seed capital, and a long incubation period leading to sale or an IPO (initial public offering)—has not markedly changed, despite reduced numbers of exits and modest overall risk-adjusted rates of return.[8] Recently, the early stage financing environment has entered a

period of dramatic realignment due to the entry of hedge funds into earlier rounds of funding for private and small publicly traded companies.

Fourth, despite intense competitive pressure, product pipelines remain highly valued because large multinational pharmaceutical companies increasingly need more products given declining productivity and pernicious attrition rates. The incessant need for pipeline products is accentuated by increasingly narrow molecular targets, large development and commercial infrastructures, and patent expirations. Moreover, the stock market appears to be quite efficient at discerning the qualitative differences amongst biopharmaceutical companies in terms of market valuations and price-earnings multiples (see Appendix 2). Thus, the conventional wisdom that new product pipelines are the lifeblood of the biopharmaceutical industry is well founded in historical operating experience and market valuations. [9,10]

Thus, large biopharmaceuticals often turn to small biotechnology companies to augment their pipelines. It estimated that in the last five years, 30-50% of new molecular entities (NMEs) came from in-licensing versus internal development. As a result, the number of pharma-biotech alliances has risen from just 69 in 1993 to 502 in 2004.[11]

While the increased value of in-licensing is often spurned as a failure of internal development, it frequently serves as a source of innovation and energy for both. Namely, big pharmaceuticals can allow internal and external programs to compete, and then choose which to move forward after proof-of-principle studies are completed.[12] The paradox is that despite the need for pipeline products, in-licensing is generally viewed as a failure within large companies due to the "not invented here" syndrome (or persistent corporate or institutional culture that avoids using research or knowledge because of its different origins). A recent industry report by the GAO concluded:

> *Recent scientific advances have raised expectations that an increasing number of new and innovative drugs would soon be developed to more effectively prevent, treat, and cure serious illnesses…Although the pharmaceutical industry reported substantial increases in annual research and development costs, the number of NDAs submitted to, and approved by, FDA has not been commensurate with these investments. From 1993 through 2004, industry reported annual inflation-adjusted research and development expenses steadily increased from nearly $16 billion to nearly $40 billion--a 147 percent increase. In contrast, the number of NDAs submitted annually to FDA increased at a slower rate--38 percent over this period. Similarly, the number of NDAs submitted to FDA for NMEs increased by only 7 percent over this period... According to experts, several factors have hampered drug development. These include limitations on the scientific understanding of how to translate research discoveries into safe and effective drugs, business decisions by the pharmaceutical industry, uncertainty regarding regulatory standards for determining whether a drug should be approved, and certain intellectual property protections.*[13]

STRATEGY FOCUSED ON CANCER CARE

Given these trends and the strengths of the team, Hana Bioscience's focus on cancer care addresses large unmet needs, focused market segment, and builds on team strengths. Hana's management believed that focusing on one physician specialty or therapeutic area was required to achieve critical mass to build a sustainable business. Hana chose cancer care which represented a niche market segment with significant unmet medical need, pricing power, and a focused commercial scope that can be addressed by an emerging company.

Cancer is a group of diseases characterized by either the runaway growth of cells or the failure of cells to die normally. Often, cancer cells spread to distant parts of the body, where they can form new tumors. Cancer is caused by a series of mutations, or alterations, in genes that control cells' ability to grow and divide. Some mutations are inherited; others arise from environmental factors such as smoking or exposure to chemicals, radiation, or viruses that damage cells' DNA. The mutations cause cells to divide relentlessly or lose their normal ability to die.

Each year, nearly 1.4 million new cases of cancer are diagnosed in the United States. Cancer is the second leading cause of death (after heart disease) in the United States, with one in four deaths in the US expected to be due to cancer. For all forms of cancer combined, the 5-year relative survival rate is 64%.[14] Despite the fact that the cancer mortality rate in the U.S. has risen steadily for the past 50 years, scientific advances appear to have begun to turn the tide. According to the National Center for Health Statistics, 2003 was the first year since 1930 that annual cancer deaths declined—the start of what researchers hope will be a long-term decline in cancer mortality.

Major treatments for cancer include surgery, radiotherapy, and chemotherapy. There are many different drugs that are used to treat cancer, including cytotoxics or antineoplastics, hormones, and biologics. Major categories include chemotherapy, targeted agents, radiotherapy, and supportive care.

Chemotherapy refers to anticancer drugs that destroy cancer cells by stopping them from multiplying. Healthy cells can also be harmed with the use of cytotoxic chemotherapy, especially those that divide quickly. Harm to healthy cells is what causes side effects. These cells usually repair themselves after chemotherapy. Cytotoxic agents act primarily on macromolecular synthesis, repair or activity, which affects the production or function of DNA, RNA or protein. Although there are many cytotoxic agents, there is a considerable amount of overlap in their mechanisms of action. As such, the choice of a particular agent or group of agents is generally not a consequence of a prior prediction of anti-tumor activity by the drug, but instead the result of empirical clinical trials.

Targeted anticancer therapies have been developed as a result of biologic insights to create products with increasingly specific molecular targeting to enhance efficacy and reduce toxicity. Most of these targeted therapies must be used in combination with

chemotherapy. Over 100 targeted anticancer agents are already on the market or in development, with the leading eight targeted therapies (Avastin, Rituxan, Herceptin, Erbitux, Gleevec, Tarceva, Sutent, and Nexavar) having estimated sales of more than $7.5 billion in 2006. Further, targeted therapies clearly dominate cancer pipelines with over 100 drugs in clinical development.[15]

Radiotherapy, also called radiation therapy, is the treatment of cancer and other diseases with ionizing radiation. Ionizing radiation deposits energy that injures or destroys cells in the area being treated - the target tissue - by damaging their genetic material, making it impossible for these cells to continue growing. Although radiation damages both cancer cells and normal cells, the latter are able to repair themselves and regain proper function. Radiotherapy may be used to treat localized solid tumors, such as cancers of the skin, tongue, larynx, brain, breast, or uterine cervix. It can also be used to treat leukemia and lymphoma (cancers of the blood-forming cells and lymphatic system, respectively).

Supportive care is another key area of the oncology market. As noted, the treatment of a cancer may include the use of chemotherapy, radiation therapy, biologic response modifiers, surgery, or some combination of all of these or other therapeutic options. All of these treatment options are directed at killing or eradicating the cancer that exists in the patient's body. Unfortunately, the delivery of many cancer therapies adversely affects the body's normal organs. The undesired consequence of harming an organ not involved with cancer is referred to as a complication of treatment or a side effect which not only cause discomfort, but may also limit a patient's ability to achieve the best outcome from treatment by preventing the delivery of therapy at its optimal dose and time. Common side effects include anemia, fatigue, hair-loss, reduction in blood platelets and white and red blood cells, bone pain, and nausea and vomiting.

The cost of cancer to the healthcare system is significant. The National Institute of Health (NIH) estimates that the overall cost of cancer in 2004 was $189.8 billion. This cost includes $69.4 billion in direct medical expenses, $16.9 billion in indirect morbidity costs, and $103.5 billion in indirect mortality costs.

According to Reuters, the global cancer market is estimated at $40 billion in 2005. In addition to being a large market, cancer care is also a highly concentrated market which makes it ideal for a small company to commercialize. Oncologists represent only 1% or 8,400 out of 635,000 total physicians in the US (often further concentrated in major metropolitan areas where specialists practice in teams). Thus, oncologists as a physician group can be promoted to by a specialty sales force (versus primary care therapeutics in areas such as cardiovascular which require thousands of sales representatives to adequately address).

BUILDING HANA'S STRATEGY, STRUCTURE, CULTURE, AND FINANCING

Reflecting on these trends in the biotech industry generally and cancer care specifically, Hana set out to develop a unique strategy relative to competitors to gain and

maintain competitive advantage, market share, and profitability. Hana decided to: (1) Focus exclusively in oncology to capture operating efficiencies, leverage core competencies, and address the passion of team members in advancing cancer care, (2) Depend on in-licensing and business development to build a diversified, stratified pipeline of oncology product candidates, (3) Concentrate on translational development and pursue a no-research, development-only (NRDO) approach to accelerate time-to-commercialization, (4) rapidly obtain a stock market listing to gain access to public capital markets by merging with an existing public entity.

First, Hana decided to focus exclusively in oncology to capture operating efficiencies, leverage core competencies, and address the passion of team members in advancing cancer care in areas of unmet medical need. Moreover, oncology is also a highly concentrated, niche market which can be commercialized by a small company with premium pricing leading to rapid value creation. In order to execute on a no-research, development-only model, the company decided it needed to be outstanding at finding new drugs through business development to build and nurture its product pipeline.

Second, the company decided to depend on in-licensing and business development to build a diversified, stratified pipeline of oncology product candidates to accelerate growth and speed-to-commercialization. Given high attrition rates in clinical development, Hana needed to be able to continuously and efficiently screen, acquire, and integrate new products and technologies into the company to achieve its ambitious objectives.

Third, the company established business development criteria with an aim to diversify risk by acquiring multiple technologies in oncology which have targets that are well validated, characterized mechanisms of action, and have strong intellectual property rights. Instead of focusing on only one product or technology platform, the management team bet that investors would support building multi-product revenue opportunities that would help Hana fund development of other follow-on technologies. They calculated that this approach would also allow Hana to establish a sales organization that would create recognition for the company as an innovator among oncologists and research institutions, which would further enhance competitiveness for business development efforts.

Finally, instead of pursuing basic research that would bind the company exclusively to one technology platform, Hana decided it's core competency was translational research to accelerate time-to-commercialization. Typically, academia achieves breakthrough discoveries through target validation and lead optimization versus translational research which is aimed at efficiently moving a product candidate from the lab to clinical development. Hana's team was built to collaborate with academia and to conduct translational research studies, such as toxicology and pharmacokinetics, to allow a timely progression to clinical trials. Of significance, the largest valuation multiples are realized between the lab and the clinic, providing a high value-added business model conducting activities that academia and research institutes are not typically capable of performing. Mark Ahn, President and CEO explained Hana's business strategy:

Hana's business model is tightly focused strategically on oncology. We are technologically agnostic, just like the physicians and patients we serve. We aim to serially acquire novel, late pre-clinical and early clinical oncology leads from academia and research institutes, as we have demonstrated to date. This will allow us to accelerate growth and speed to commercialization by starting with actual product leads versus targets. It also will allow us to exploit development cost efficiencies from our therapeutic focus in oncology, and to realize transformational valuation multiples from the lab to the clinic to proof of principle and beyond. We believe there's a large gap to be an efficient, research cooperative from which we can drive a sustainable, high value-added business and growth for our investors. [16]

While many small companies become cults of the founders' personality, the management team felt strongly that sustainable growth in a highly complex life science business required careful attention to building a cohesive team-based culture. The culture was crafted by the first four employees and is continuously revisited and discussed at meetings to ensure consistency and relevance as the company grows. Hana's approach was to frame culture as "*How* we get things done" and a belief that striving to be part of something larger than oneself is a universal human value. Moreover, the leadership team felt that having a unifying culture would also provide guidance to all levels of the organization making challenging and complex multifunctional decisions.

Hana's unique culture was formed around four elements. First, "Enhancing the lives of patients through bold and continuous innovation" represents a unifying theme irrespective of the functional expertise of a particular team member. This was crafted with a belief that advancing cancer care was challenging, significant, and worth the effort of those who committed their professional lives to improving treatments. It was also based on the belief that achieving significance was a fundamental human goal and a guiding force for decision making. For example, everyone is expected to place patient welfare first which makes safety paramount to all other issues such as timelines, milestones or financial pressures facing the company.

Second, another element of Hana's high performance culture "developing extraordinary team members who can realize their full potential, talent and imagination" reflected the high expectations for performance and specialized knowledge each individual team member. Regardless of the expertise of any individual on the team, Hana also signaled that teamwork was absolutely required.

The third aspect of Hana's culture is, "creating high performing teams that are committed to the unlimited success of one another, as well as our patients, partners, and shareholders." This reflects the critical level of collaboration required in order to be efficient and effective at moving multiple products at multiple stages of development forward simultaneously. In an environment of high performing knowledge workers with highly specialized skills, the management team strongly believes that developing a tight knit group who cares deeply about one another and fiercely committed to a common mission will ultimately determine the success or failure of Hana.

The forth and final element of Hana's culture, "seeking goodness and grace in others with the highest standards of integrity," signaled the founding team's belief in the fundamental good nature of others. It was also a reflection of the unlimited power and energetic commitment required to be successful in advancing cancer care. This element of company culture was inspired by a line by poet John Keats, *"I am certain of nothing but the holiness of the heart's affection and the truth of imagination."*

Combining these four elements, Hana summarizes their mission and strategy as P^3C (People, Products, Pipeline, and Culture) as follows:

Hana Biosciences, Inc. (NASDAQ: HNAB) is a South San Francisco, CA-based biopharmaceutical company that acquires, develops, and commercializes innovative products to advance cancer care*. We are committed to creating value by building a world-class team, accelerating the development of lead product candidates, expanding our pipeline by being the alliance partner of choice, and nurturing a unique company culture. We are committed to P^3C:*

- ***People****: Building a world-class team with leading core competencies in cancer drug development and commercialization.*
- ***Products****: Acquiring and accelerating the development and commercialization of innovative oncology product candidates.*
- ***Pipeline****: Expanding our pipeline by being the partner of choice for suppliers, researchers, and alliance partners.*
- ***Culture****: Nurturing a unique company culture focused on patients, developing extraordinary team members, creating high performing teams, and seeking goodness and grace in others with the highest standards of integrity.*

Source: Hana Biosciences company presentation, www.hanabiosciences.com

Another critical element of Hana's business model is obtaining financing to achieve and accelerate its corporate goals. The traditional financing approach of obtaining venture capital seed funding was dismissed because venture investors typically want Board of Directors' control, as well as focus on a single asset or platform to gain a value multiplier which can be realized through a sale, IPO or other exit strategy.[17] This is predominantly the case because most venture capital funds have 10 year life spans at the end of which all investments must be liquidated and returned to investors. Thus, the primacy of focus for venture capitalists effectively dissuades portfolio companies from internal diversification (since they are already diversified through multiple investments and need to be able to raise additional investment funds).[18]

Instead, Hana completed a reverse-merger with an illiquid, publicly traded over-the-counter (OTC) company only 15 months after inception to gain access to public capital markets early in the company's development. Essentially, management bet that generating broad investor interest in Hana stock based on its strategy and progress would outweigh the substantial costs of being a publicly traded company (i.e., Sarbanes-Oxley, SEC requirements, audits, etc).

Hana moved from the OTC (over-the-counter) market to the Amex (American Stock Exchange) after eight months, then to the NASDAQ six months afterwards while raising successive rounds of financing with increasingly larger banks and investors. In the first year since going public, Hana stock volume went from 3,000 shares a day for the first 3 months to over 200,000 shares a day. The company obtained biotechnology analyst research coverage from nine different investment banks, raised over $75 million with successively larger investors, and progressed from about 40 initial investors to over 3,000 shareholders.

Most importantly, from the perspective of Hana management, operational flexibility was greatly enhanced which allowed the company to use its stock currency to rapidly build a stratified and diversified pipeline. “In less than three years, Hana licensed multiple products never worrying about how the addition was going to impact the exit strategy of any one of our investors,” John Iparraguirre, Vice President and CFO reflected. “While we experienced major investor turnover along the way, the changes have lead to very healthy shifts in our investor base from venture stage to early public stage funds.”

In sum, Hana’s management was focused on building a premium oncology company by building a strong, experienced team, accelerating the development of lead product candidates, expanding their pipeline by being the alliance partner of choice for academic and research organizations, and nurturing a unique company culture. With the company’s unique strategy, structure, culture, and financing approach, Ahn explained the company’s five-year vision:

> *Our vision is very clear. Our intent is, by 2010, to be a fully integrated biopharmaceutical company with at least two innovative drugs in the market, reach $100 million in revenues, and aim for at least five product pipeline candidates. All of these goals are driven by a unique culture, which is focused, relentless, and flexible.*[19]

CASE A: SHOULD HANA BIOSCIENCES DOUBLE ITS PIPELINE THROUGH PRODUCT ACQUISITION?

After two years from private to public company, Hana Biosciences entered 2006 with significant momentum. The small cap biotech company went from one person start-up to completing two financings, obtaining a public listing on the American Stock Exchange (and about to apply for a NASDAQ listing), and attaining investment bank equity research coverage from six leading biotech analysts. This was all on the basis of acquiring and developing three pre-clinical stage products: Zensana (ondansetron HCI) Oral Spray, Talvesta (talotrexin), and Ropidoxuridine (IPdR) respectively.

On the basis of its three product pipeline, the company developed strong support from the biotechnology financial analyst community placing a uniform "buy" rating on Hana's stock. Investors appeared to be signaling that focus and execution on the products already in the company were expected to continue expanding value.[20] Oppenheimer, for example, initiated research coverage of Hana with:

> *We are initiating coverage of Hana Biosciences, Inc. with a Buy rating and a 12-month target price of $15 based on a risk-adjusted net present value (rNPV) analysis and supported by a real-options analysis. As a relatively undiscovered story with three oncology candidates, an impressive management team, and multiple milestones expected over the next six months, we believe Hana is a compelling opportunity for risk-tolerant investors.*
>
> *In our opinion, Zensana is a significantly underappreciated asset that alone is worth $7-$8 per share. This anti-emetic oral spray has the same active ingredient as GlaxoSmithKline's Zofran (ondansetron), which generated $1.2 billion in sales in 2005…We believe Talotrexin holds the most upside potential of Hana's three product candidates. The drug is designed as an improved version of an established class of cytotoxic therapies (antifolates), has demonstrated promising preclinical and early clinical results, and is poised to deliver significant news flow over the coming year…IPdR, the third clinical candidate in Hana's stable, is an orally available prodrug of IUdR, which is being developed as a radiosensitizer in various solid tumors and brain cancers.*[21]

However, just when Hana Biosciences appeared set to tightly focus on assets already in the pipeline, the team stumbled across an intriguing set of distressed products known as targeted sphingosomal cancer therapeutics which were originally developed by researchers at the University of British Columbia and currently in the possession of Inex Pharmaceuticals, a financially troubled Canadian biotech company.

Sphingosomal encapsulation is a new generation liposomal drug delivery platform, which significantly increases tumor targeting and duration of exposure for cell-cycle specific anticancer agents. When used in unencapsulated form, chemotherapeutic drugs diffuse indiscriminately throughout the body, diluting drug effectiveness and causing toxic side effects in the patient's healthy tissues. The proprietary sphingosomal

formulation technology permits the loading of a high concentration of therapeutic agent inside the lipid envelope, promotes accumulation of the drug in tumors, and prolongs the release of the drug at disease sites. As a result, compared to free drugs, agents encapsulated in sphingosomes have been shown to deliver more of the therapeutic agent to a targeted disease site over a longer period of time, thus increasing the efficacy of the drug without increasing the toxicity in healthy, non-targeted tissues.[22]

There were three drugs using the sphingosomal encapsulation: Marqibo™ (sphingosomal vincristine), Alocrest™ (sphingosomal vinorelbine), and Sphingosomal topotecan. The lead drug in the portfolio was Marqibo™, a novel, targeted sphingosomal formulation of vincristine that has shown promising Phase II anticancer activity in patients with non-Hodgkin's lymphoma (NHL) and acute lymphoblastic leukemia (ALL).Due to selective targeting, Marqibo™ delivers ten times more drug into the tumor than does unencapsulated vincristine. Based on clinical results in over 600 patients to date, Marqibo™ will enter pivotal trials by year end 2006.

In addition, the remaining products in the licensing opportunity included Alocrest, a targeted formulation of a microtubule inhibitor that is approved for use as a single agent or in combination with cisplatin for the first-line treatment of unresectable, advanced non-small cell lung cancer. The third product was Sphingosomal Topotecan, a proprietary, targeted formulation of a topoisomerase I inhibitor that is approved for use in relapsed small-cell lung cancer and in relapsed ovarian cancer. Both of these products were scheduled to enter human clinical trials within a year.

While the targeted sphingosomal encapsulated anticancer agents were scientifically exciting, the Hana management team was concerned that a prior rejection by the FDA would be controversial for investors. Further, the lead licensing candidate, Marqibo, had itself become a political issue and particularly infamous example of denying access to life saving technologies despite widely acknowledged problems with clinical study conduct. As noted in a terse *Wall Street Journal* editorial entitled "Pazdur's Revenge" published after the FDA denied Marqibo's first new drug application:

> *At issue was a therapy called Marqibo for aggressive non-Hodgkins lymphoma for patients who relapse following initial treatment… there was plenty of evidence before the panel to suggest it might have been a valuable addition to the anti-cancer arsenal, given how much variability there is in the way individual patients respond to different drugs.*
>
> *And since there are no other drugs approved for relapsed non-Hodgkins, it should have been eligible for accelerated approval. But Dr. Pazdur [FDA oncology drug chief] explained that since there are a number of drugs for other conditions being used "off-label" to treat relapsed non-Hodgkins, there was no great urgency concerning Marqibo.*
>
> *Just as worrying as the fate of this individual therapy was the apparent relish with which some of the panelists dismissed the efforts of Marqibo's makers at the Enzon*

company and fired back at the patient activists who've been uppity enough to suggest faster access to developmental drugs…[23]

The management team called a Board teleconference at 6 am to consider the opportunity. Sitting around the conference table with a box of Starbucks coffee and Krispy Kreme donuts, Ahn began, "Good morning and thanks for convening on such short notice. In the course of routine business development due diligence on a completely different preclinical compound in CLL [chronic lymphocytic leukemia], we literally stumbled on a unique situation and opportunity to license three targeted sphinogosomal agents developed by Dr. Pieter Cullis at the University of British Columbia, then subsequently developed by Inex Pharmaceuticals in Vancouver. The initial efforts were unsuccessful not because of drug performance in clinical trials, but due to a number of clinical trial deviations which we believe can be readily addressed with a quality clinical trial."

Alex Tkachenko, Vice President, Corporate Development and Strategic Planning provided an overview of the proposed licensing deal terms. "We can license these assets on very favorable terms with built in flexibility for Hana. Of the $11.5 million up-front payment, we pay Inex $1.5 million in cash and the remainder in Hana stock. Additional milestones can be paid in stock or cash at our choosing. Further, single digit royalty rates provide high margins if we can get these drugs approved."

"Vincristine is a standard chemotherapeutic agent used in most lymphoma and leukemia regimens in approximately 60,000 patients annually. Vincristine's activity is limited by it's short half-life and it's inability to be dose escalated beyond a 2 mg total dose because of neurotoxicity," offered Greg Berk, Vice President and Chief Medical officer, as well as a hematologist-oncologist who treated many leukemia patients. "Not only does Marqibo have a significantly longer half-life, but phase I and II studies with Marqibo have shown that patients can tolerate doses which are 100% greater than conventional vincristine. The result of the improved pharmacokinetic profile and dose intensity is improved efficacy."

Fred Vitale, Vice President and Chief Business Officer went further, "Marqibo is an attractive drug for Hana to commercialize because only 1,500 hematologist-oncologists will need to be targeted to maximize revenues."

"Inex needs this deal to survive. They have no access to the capital markets because their balance sheet is upside down. This deal gives them a way to eliminate their debt and restart their company around other technology platforms, added John Iparraguirre, Vice President and Chief Financial Officer. However, he cautioned, "a pivotal trial program for Marqibo would cost *at least* an extra $20 million that we don't currently have in the budget or in the bank. This license will require us to raise capital and dilute current shareholders in order to develop these assets."

After a great deal of debate and several cups of coffee, it was clear Board members were concerned about the impact on Hana's strategic direction and operational focus. As

one Board member soberly pointed out, “liposomal encapsulation is nothing new. Successes in this area have been very limited despite several efforts to expand the therapeutic index of chemotherapy agents.” Another stated, “We shouldn’t dilute our operational focus. Wall Street may also believe that we don’t have confidence in the products we already have.” Yet another Board member said, “Marqibo was turned down by the FDA. Should we double our pipeline and substantially increase our operating costs when Marqibo still has a cloud over it?” Finally someone asked the CEO, “Mark, what *exactly* are you and the management team requesting?”

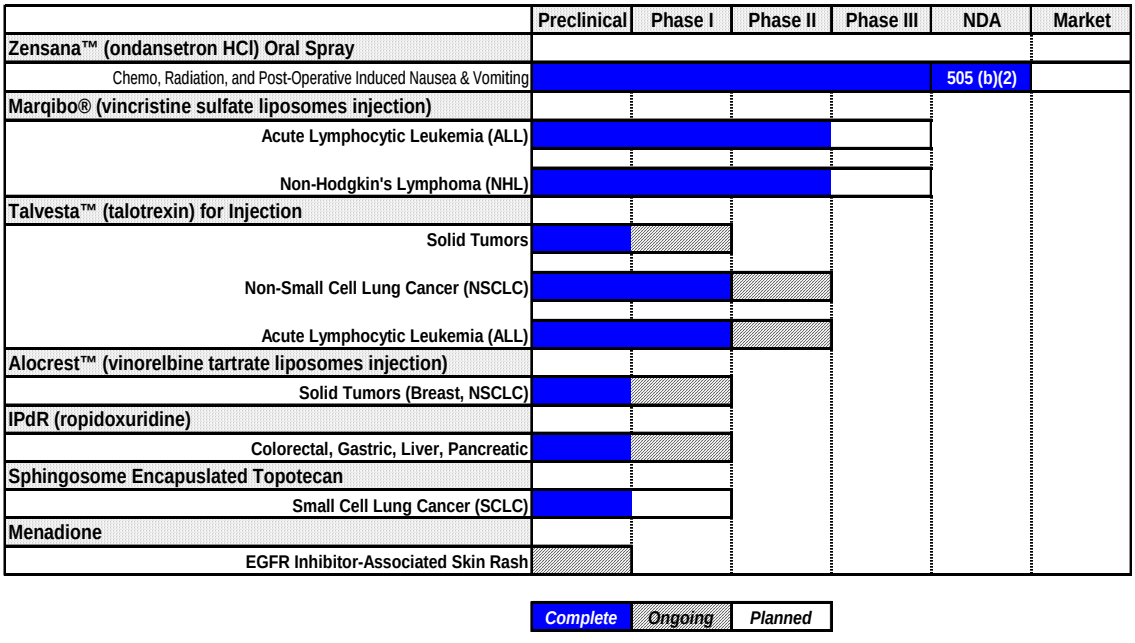
As the management team looked at each other and the Voicepoint teleconferencing device located on the meeting room table, Ahn replied “We would like to proceed with licensing the Inex targeted chemotherapy agents as negotiated. We believe that these agents would substantially add to our portfolio while leveraging our core capabilities, carry low-to-moderate development risk with rapid cycle times, and will ultimately be accretive to Hana shareholders.” An uncomfortable silence of about 30 seconds elapsed as Board members were considering the initiative…

CASE B: SHOULD HANA BIOSCIENCES PURSUE COMMERCIALIZATION OR PARTNER TO LOWER RISK?

As the New Year opened, the management team met to assess the prior year and discuss challenges ahead. As they reflected on Hana's first full year as a public company, Mark Ahn, President and CEO remarked, "during the year we met and exceeded our objectives in terms of building and moving the pipeline forward. We strengthened the core capabilities of the team in key functional areas such as clinical, regulatory and manufacturing. We achieved these goals on time and on budget. We also built shareholder value through our progress. Last year's achievements included completing pivotal trials and filing a new drug approval application for Zensana™, strengthening our pipeline with the addition of four drug candidates, and expanding investor reach with a NASDAQ listing."

As a result of a significant business development effort, Hana built a fully integrated, diversified pipeline of seven products (see figure 2). With a full pipeline of 7 products, five of which were already in clinical trials, Hana proved it could build a pipeline but still lacked revenues and commercialization.

Figure 2: Hana's pipeline of seven product candidates



As the management team gathered to reflect on the budget and goals for the following year, however, they quickly realized that current resources were insufficient to complete the bold strategic gambit which the company had communicated to investors. The firm's three primary goals—commercialize Zensana, execute a pivotal clinical trial leading to approval for Marqibo, and move Talvesta forward in Ph II clinical trials—alone surpassed the cash balance on hand for the company and required difficult strategic choices for the management team.

Hana expected to commercially launch Zensana in the United States in the first half of 2007. The company anticipated that revenues from Zensana would help offset at least a portion of development costs and reduce dependence on external financing. Additionally, they planned to assemble a specialized oncology sales force of approximately 30 people that could educate oncologists and nurses in using Zensana. Moreover, they intended to leverage this sales force in commercializing future oncology products.

Fred Vitale, Vice President and Chief Business offer stated emphatically, "We only have one chance to launch Zensana. This is not a pay-as-you go business. Let's spend the money for a rapid launch and give this product a chance to be successful."

John Iparraguirre, Vice President and CFO replied, "I don't want to be overly cautious, but how are we going to pay for the launch of Zensana and effectively develop the rest of the pipeline? We simply don't have the budget to do everything."

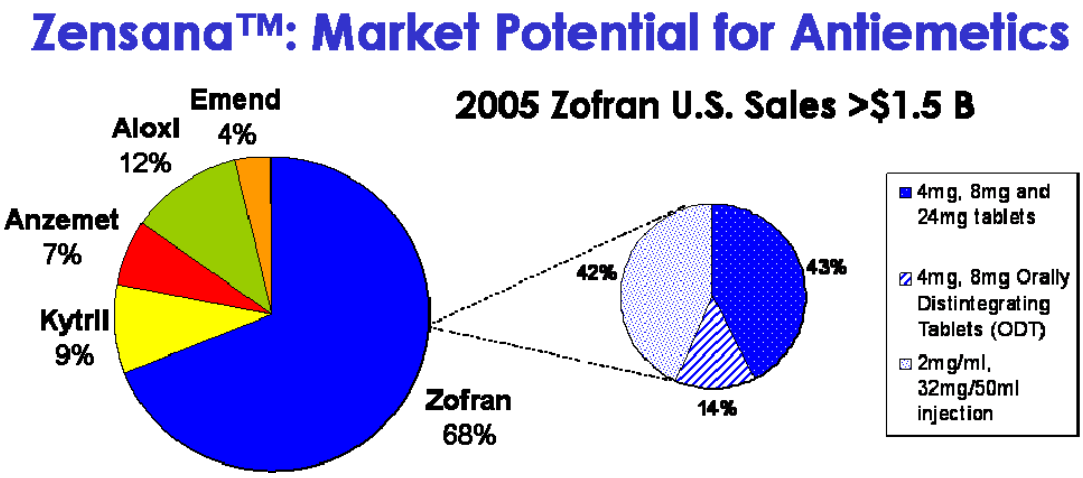
About Zensana

Zensana™ (ondansetron HCl) oral spray is the first multidose oral spray 5-HT3 antagonist. Zensana™ utilizes a micro mist spray technology to deliver full doses of ondansetron to patients receiving emetogenic chemotherapy. Ondansetron is approved to prevent chemotherapy and radiation-induced, and post-operative nausea and vomiting.Many patients receiving chemo and radiation therapy experience dysphagia or have difficulty swallowing oral medicines. Drug delivery via a spray is convenient and offers a desirable alternative to tablets and other forms of ondansetron.

Zensana appeared to present an attractive commercial opportunity in a competitively intense market (see figure 3). The management of chemotherapy-induced nausea and vomiting (CINV), radiation-induced nausea and vomiting (RINV), and post-operative nausea and vomiting (PONV) is a critical aspect of cancer patient care. It is estimated that approximately 70-80% of 500,000 patients receiving chemotherapy per year are addressable with antiemetic therapies.

Since the introduction of Zofran® (ondansetron), the 5-HT3 class of treatment has grown to approximately $2.0 billion in the US alone with the introduction of three other US marketed antiemetics – Kytril (granisetron) from Roche, Anzemet (dolasetron) from Sanofi-Aventis, and most recently, Aloxi (palonosetron) from MGI Pharma. 2005 US sales for branded Zofran® were approximately $1.5 billion, which represented 68% market share of the total antiemetic market.

Figure 3



Source: IMS (2006)

In addition to the currently branded antiemetics, there will be generic versions of ondansetron after Zofran goes off patent in December 2006. Dr. Reddy's Lab, Par Pharmaceuticals, Mayne Pharmaceuticals, and Teva Pharmaceuticals, have all submitted generic applications for the three formulations of ondansetron. After the launch of the generics, each will have 180 day exclusivity for the sale of their respectively approved formulations before multiple versions can be launched.

Market research was conducted to survey physician and payor utilization, as well as perceptions of current and emerging antiemetics. Despite the competitive intensity, a survey of hematologists-oncologists concluded 90% or 9 out of 10 oncologists believe Zensana™ is more convenient for their patients than a tablet for the prevention of chemo-induced nausea and vomiting. In addition, the survey indicated that oncologists would use Zensana™ (ondansetron oral spray) *prior* to chemotherapy in at least 25% of their patients. In addition, 66% of oncologists surveyed responded that they would prescribe Zensana™ (ondansetron oral spray) *after* chemotherapy to >50% of their patients treated with moderate-to-highly emetogenic chemotherapy. Thus, while the primary use of Zensana™ will be in the post-chemotherapy setting, there is also a significant upside opportunity to use Zensana™ for the entire treatment cycle. Finally, Zensana's product profile appeared to offer an attractive alternative to existing formulations by concluding that 48% of physicians agree that *the* most important product attribute for oral 5-HT3s' is: "[product] can be used easily by patients who are experiencing nausea & vomiting, in contrast to swallowing a tablet."

Despite the favorable target product profile of Zensana, several financial analysts questioned the wisdom of Hana launching the product versus finding an established alliance partner who already possessed significant commercial infrastructure required to successfully launch a biopharmaceutical drug.

This is a great management team facing a tough launch in the form of Zensana. We actually find this launch fascinating since factors completely out of Hana's control could turn it into a nightmare. While we think the odds of that are slim, it will be interesting to see how good management really is by determining how fast they pull the plug…Of more specific interest for Zensana are the potential outlicensing deals for indications other than oncology. A good deal or two could really benefit the company.[24]

Another analyst worried that competitive intensity as a result of multiple branded and generic products would significantly reduce the pricing power of Zensana and lead to modest launch performance.

HNAB stock has been relatively weak during the last couple of weeks. We believe one of the main reasons is the approval/launch of several generic versions of Zofran (ondansetron) by as many as seven different companies. Hana has Zensana, which is an oral spray version of Zofran with a unique method of delivery that works by going directly into the blood through the oral cavity and avoiding first pass metabolism. The seven companies involved in the impending generic war are Abraxis BioScience (ABBI), Boehringer Inglheim, Dr. Reddy Laboratories (RDY), Hospira (HSP), PAR Pharmaceutical (PRX), Teva Pharmaceutical (TEVA) and Wockhardt. Details of the different generic versions are provided in the table below.

We continue to believe that it would be in the best interest of Hana to partner Zensana. Currently, the company is in the midst of pre-launch activities for Zensana including building out a sales force in preparation for expected approval on April 30 (PDUFA date). [25]

While Zensana presented an attractive commercial opportunity, Hana was faced with a critical decision of whether to partner the product with a company who already had an established commercial presence to lower risk or go it alone and build commercialization capabilities. Launching Zensana independently, however, forced other tradeoffs in the company's pipeline development. Of particular concern to management was allocating resources to accelerate the conduct of a large multinational trial for Marqibo, which could lead to approval of a larger and more competitive drug compared to Zensana. Given its current cash position, the management team considered its options to build value–launch Zensana and delay the Marqibo clinical trial, find an alliance partner to launch Zensana, conduct the Marqibo trial and delay the launch of Zensana, or do a dilutive financing and attempt to conduct the entire strategy alone.

"The market clearly sees that if we launch Zensana ourselves we'll need to raise significant capital and be dilutive to shareholders to simultaneously develop the rest of our pipeline. This is why our stock is weak," observed CFO John Iparraguirre. "Licensing out Zensana lowers operational and financial risk. Hana would not have to raise money for an additional two years and we can complete the critical pivotal trial with Marqibo, as well as make significant progress with the remainder of the pipeline."

Fred Vitale, Chief Commercial Officer emphatically countered, “We have earned the right to launch Zensana. Building our commercial presence and executing on our clinical progress is precisely why we started this company and the market will reward us for a successful launch. Let’s not quit while the prize is in our grasp.”

Hana could stay the course to keep all assets in the company and bet that operational execution would allow it to continue to raise additional financing on favorable terms. On the other hand, several small companies recently gained FDA approval only to experience poor product launches leading to drastic reductions in market value and operational flexibility. Ahn reflected, “One misstep with Zensana may jeopardize the entire company, but if we can pull off a successful launch we have the opportunity to become one of the very few sustainable, fully integrated biopharmaceutical companies.”

APPENDIX A: BIOPHARMACEUTICAL DRUG DEVELOPMENT

The average development costs per product are over $1.0 billion and 12 years from research to approval. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved. For the drugs that progress into human clinical trials the overall attrition rates is 11%, with oncology at 5% (although biopharmaceuticals tend to have a lower overall clinical approval success rate compared to traditional pharmaceutical firm products).[26,27]

The table below provides an outline of the drug development process, success rate of drugs and the length of time each step takes.

Figure 4: Drug Development

			Clinical Trials						
	Preclinical Testing	File IND at FDA	**Phase I**	**Phase II**	**Phase III**	File NDA at FDA	**FDA**		**Phase IV**
Years	3.5		1	2	3		2.5	12 Total	Additional Post marketing testing required by FDA
Test Population	Laboratory and animal studies		20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers		Review process / Approval		
Purpose	Assess safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness, monitor adverse reactions from long-term use				
Success Rate	5,000 compounds evaluated		5 enter trials				1 approved		

New biopharmaceutical products generally progress through the following steps: (1) pre-clinical testing to establish biological activity against the targeted disease, (2) Investigational New Drug Application (IND) filing to allow human clinical trials, (3) Phase I, II and III clinical trials to establish statistically significant safety and efficacy, and (4) New Drug Application (NDA) for approval for a specific type and stage of disease.[26]

Further, under the Food and Drug Administration Modernization Act of 1997 (FDAMA), the FDA has established a number of processes—Fast Track, Priority Review, and Accelerated Approval—to accelerate the review of medicines which treat life threatening unmet medical needs such as cancer.[28] Fast Track review refers to a process for scheduling meetings to seek FDA input into development plans, option of submitting a New Drug Application in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. Priority Review is a designation for an application that accelerates the review

period to 6 months for FDA action versus the standard review period of 10 months (i.e., Ethyol (amifostine) to reduce post-radiation xerostomia for head and neck cancer where the radiation port includes a substantial portion of the parotid glands by US Biosciences). Accelerated Approval or Subpart H Approval is a program which allows the FDA evaluation to be performed on the basis of a surrogate marker (a measurement intended to substitute for the clinical measurement of interest, usually prolongation of survival) that is considered likely to predict patient benefit (i.e., Velcade (bortezomib) for the treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression on the last therapy by Millennium Pharmaceutical).

APPENDIX B: FINANCIAL ANALYST EARNINGS MODEL[29]

($ in thousands, except per share data)

FY ending December 31	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Revenue							
Zensana	$ -	$ -	$ -	$ 27,202	$ 93,645	$ 227,147	$ 350,902
Marqibo	-	-	-	-	-	24,347	75,293
Talvesta	-	-	-	-	-	2,915	137,296
IPdR	-	-	-	-	-	-	42,418
Total Revenue	-	-	-	**27,202**	**93,645**	**254,410**	**605,909**
Total COGS (1)	-	-	-	6,392	22,007	57,841	118,515
Gross Profit	-	-	-	**20,809**	**71,638**	**196,569**	**487,394**
Operating Expenses							
Research & Development (2)	4,547	6,366	21,052	29,568	39,420	47,974	61,495
Licensing & Milestone (3)	-	50	2,050	8,050	9,050	9,050	9,050
Sales & Marketing (4)	-	-	440	4,352	9,365	11,600	11,888
General & Administrative (5)	2,809	3,793	10,642	16,174	13,967	12,721	30,295
Total Operating Expenses	7,355	10,209	34,184	58,144	71,802	81,344	112,729
Operating Income	**(7,355)**	**(10,209)**	**(34,184)**	**(37,334)**	**(163)**	**115,225**	**374,665**
Other income (expenses)							
Interest income (6)	26	186	1,151	694	864	3,171	8,683
Depreciation and Amortization	-	-	-	-	-	-	-
Other income (expenses)	(1)	(20)	(22)	(24)	(26)	(29)	(32)
Income (Loss) Before Tax	(7,330)	(10,043)	(33,054)	(36,664)	675	118,367	383,316
Tax (7)	-	-	-	-	-	(12,300)	(145,660)
Net Income (Loss)	**$ (7,330)**	**$ (10,043)**	**$ (33,054)**	**$ (36,664)**	**$ 675**	**$ 106,068**	**$ 237,656**
Shares Outstanding (8)	10,792	17,662	28,743	28,743	28,743	28,743	28,743
Fully-Diluted Shares (8)	13,149	22,564	34,592	34,592	34,592	34,592	34,592
EPS - Basic	**$ (0.80)**	**$ (0.57)**	**$ (1.15)**	**$ (1.28)**	**$ 0.02**	**$ 3.69**	**$ 8.27**
EPS - Diluted	**$ (0.80)**	**$ (0.57)**	**$ (1.15)**	**$ (1.28)**	**$ 0.02**	**$ 3.07**	**$ 6.87**
P/E Ratio *(price as of close 9/26/06)*	**N/M**	**N/M**	**N/M**	**N/M**	**N/M**	**2.26**	**1.01**

MARGIN ANALYSIS	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Gross Margin	NM	NM	NM	77%	77%	77%	80%
COGS	NM	NM	NM	24%	24%	23%	20%
G & A	NM	NM	NM	59%	15%	5%	5%
R & D	NM	NM	NM	109%	42%	19%	10%
Operating Income	NM	NM	NM	NM	0%	45%	62%
Net Income	NM	NM	NM	NM	1%	42%	39%

YOY GROWTH ANALYSIS	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Revenue	NM	NM	NM	NM	244%	172%	138%
COGS	NM	NM	NM	NM	244%	163%	105%
R & D	NM	40%	231%	40%	33%	22%	28%
G & A	NM	35%	181%	52%	-14%	-9%	138%
Operating Income	NM	NM	NM	NM	NM	NM	225%
EPS	NM	NM	NM	NM	NM	NM	124%

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