

# SECURITIES AND EXCHANGE COMMISSION

## FORM 424B3

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### FILER

#### **Hana Biosciences Inc**

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**OFFERING PROSPECTUS**

**Hana Biosciences, Inc.**

**7,340,317 Shares**

**Common Stock**

The selling stockholders identified on pages 55-57 of this prospectus are offering on a resale basis a total of 7,340,317 shares of our common stock. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol "HNAB." On April 29, 2005, the last sale price for our common stock as reported on the OTC Bulletin Board was \$1.55.

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**The securities offered by this prospectus involve a high degree of risk.  
See "Risk Factors" beginning on page 6.**

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**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.**

The date of this Prospectus is April 29, 2005.

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## PROSPECTUS SUMMARY

*This summary provides a brief overview of the key aspects of this offering. Because it is only a summary, it does not contain all of the detailed information contained elsewhere in this prospectus or in the documents included as exhibits to the registration statement that contains this prospectus. Accordingly, you are urged to carefully review this prospectus in its entirety.*

### Our Business

We are a development stage biopharmaceutical company focused on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. We currently have three product candidates in early-stage development - PT-523, for the treatment of a variety of solid tumor cancers; IPdR, being developed primarily for the treatment of brain cancers; and ondansetron lingual spray, which is being developed to alleviate chemotherapy-induced nausea and vomiting. To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

**PT-523**, our lead product candidate, is an antifolate, cytotoxic agent (i.e., substance harmful to the structure and function of cells) designed for the treatment of solid tumors and hematological cancers. PT-523 is currently in Phase I clinical trials being conducted at the Dana-Farber Cancer Institute, Massachusetts General Hospital and Beth-Israel Deaconess Hospital. This study commenced in April 2004 and is expected to involve 25-40 patients with seven already having received doses of PT-523. The primary purposes for this study are to evaluate the safety of PT-523 when administered intravenously to patients with solid tumors and who have failed curative or survival prolonging therapy or for whom no such therapies exist, to establish the maximum tolerated dose and identify the dose limiting toxicities associated with PT-523. In February 2005, an open-label multicenter, multinational Phase I and II study of PT-523 was commenced in the treatment of relapsed or refractory non-small cell lung cancer or “NSCLC”. The primary objectives of the Phase I portion of this study are to: (1) evaluate the safety of PT-523 when administered on Days 1 and 8 of a 21-day cycle to NSCLC subjects who have failed curative or survival prolonging therapy or for whom no such therapies exist; and (2) establish the maximum tolerated dose and identify the dose limiting toxicities of PT-523. The primary objectives of the Phase II portion of this study are to evaluate the activity of PT-523 as therapy in subjects with NSCLC who have progressed on or following first-line therapy’s, as measured by overall survival. A total of 120 patients are expected to enroll in the Phase I and II clinical trials. While some treatment options are currently available, we believe that a significant opportunity exists to improve the therapeutic options for patients with the progressive form of this cancer. This study will evaluate the anti-tumor activity of PT-523 among patients with previously treated non-small cell lung cancer. Further, we anticipate initiating a Phase II clinical trial in cervical cancer before the end of 2005.

**IPdR**, our second product candidate, is a radiation therapy sensitizer that is designed for the treatment of certain types of brain cancers. Radiation therapy deposits energy that injures or destroys cells in the treated area. Radiosensitizers, when used in combination with radiation therapy, potentially make the tumor cells more likely to be damaged by the radiation therapy. IPdR is an orally administered prodrug for 5-iodo-2’-deoxyuridine, or IUdR. Prodrugs are compounds that are converted within the body into active form that has medical effects. A prodrug can be useful when the active drug is too toxic to administer systemically. IUdR would be an effective radiosensitizer, but its systemic toxicity limits the duration and dosage such that its efficacy is limited. We anticipate being able to commence a Phase I clinical trial of IPdR by mid to late 2005.

**Ondansetron lingual spray**, or “OLS,” our most recently-acquired product candidate, is a novel delivery system that utilizes the vast and highly-absorptive surfaces of the inner lining of the mouth, known as the oral cavity (including the area under the tongue) to deliver the drug ondansetron, the most widely used drug to prevent chemotherapy-induced nausea and vomiting, directly into the bloodstream. Administration of ondansetron lingual spray (i.e., spraying on the tongue) will potentially decrease the time necessary to achieve effective concentrations in the bloodstream, which we believe will more rapidly alleviate nausea and vomiting than conventional oral tablet dosage forms of ondansetron currently available. We licensed our rights to develop and commercialize OLS in the US and Canada from NovaDel Pharma, Inc. pursuant to the terms of an October 2004 license agreement. Hana has recently completed a pilot pharmacokinetic study in which an investigational formulation of OLS and the 8 mg Zofran® tablet were each administered to 9 healthy adult male volunteers. The study demonstrated that the lingual spray technology was able to efficiently deliver ondansetron and to produce a pharmacokinetic profile similar to the currently marketed oral tablet. In addition, the LS product led to faster appearance of measurable levels of ondansetron in the blood (twenty minutes shorter for 8 mg OLS versus 8 mg tablet) and to an increase in total amount of drug delivered over the first twenty minutes after dose administration. Based on successful results of this pilot pharmacokinetic trial in healthy volunteers, we intend to file an Investigational New Drug (IND) Application to commence an abbreviated clinical development program designed to support a 505(b)(2) submission, a form of New Drug Application (NDA) that relies on data in previously approved NDAs and published literature. If the results are successful, we expect the oral spray version to be available in 2007.

To date, we are only in the early stages of development of our product candidates, which is a very lengthy and expensive process. None of our product candidates have been approved for sale by the U.S. Federal Drug Administration or any other regulatory body and we do not expect to have obtained such approvals for several years, if ever. Accordingly, we have not received any commercial revenues to date and, until we receive the necessary regulatory approvals, we will not have any commercial revenues. Further, we will require substantial additional capital in the future in order to fund the development of our product candidates to completion. We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the year ended December 31, 2004 we had a net loss of \$7,329,832 and since our inception in December 2002 through December 31, 2004, we have incurred a net loss of \$8,026,158. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable.

Our executive offices are located at 400 Oyster Point Boulevard, Suite 215, South San Francisco, California 94080. Our telephone number is (650) 588-6404 and our Internet address is [www.hanabiosciences.com](http://www.hanabiosciences.com).

### **Recent Developments**

On April 22, 2005, we sold in a private placement 3,849,472 shares of our common stock at a price of \$1.28 per share resulting in gross proceeds of approximately \$4.93 million. In addition to the shares of common stock, the investors also received 5-year warrants to purchase an aggregate of 1,154,826 shares at an exercise price of \$1.57 per share. In connection with the private placement, we paid an aggregate of approximately \$315,000 in commissions to placement agents and issued 5-year warrants to purchase an aggregate of 344,159 shares of common stock at a price of \$1.57 per share.

### **Risk Factors**

As with most pharmaceutical product candidates, the development of PT-523, IPdR and OLS is subject to numerous risks, including the risk of delays in or discontinuation of development from lack of financing, inability to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are a development stage company with a very limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled “Risk Factors” beginning on page 6 of this prospectus.



## Corporate History

We were incorporated under Delaware law in December 2002 under the name Hudson Health Sciences, Inc. In July 2004, we completed a merger with Email Real Estate.com, Inc., or “EMLR,” a publicly-held Colorado corporation formed in March 2000. At the time of the transaction, Email Real Estate.com had only nominal assets and no operating activities. In connection with this merger transaction, a wholly-owned subsidiary of EMLR merged with and into us, with our company remaining as the surviving corporation and a wholly-owned subsidiary of EMLR. We also changed our name in connection with the merger to Hana Biosciences, Inc. In exchange for their shares of capital stock, the former stockholders of Hudson received capital stock of EMLR representing approximately 85 percent of the outstanding voting power of EMLR. In addition, upon completion of the merger, all of the officers and directors of EMLR resigned and were replaced by our officers and directors. Because the merger resulted in a change in ownership and in the management of EMLR, the transaction was accounted for as a reverse acquisition, with us as the accounting acquiror and EMLR as the accounting acquiree.

In September 2004, the shareholders of EMLR approved a plan to reincorporate the company under Delaware law. The reincorporation was accomplished by merging EMLR with and into Hana Biosciences, a Delaware corporation, with Hana remaining as the surviving corporation. In connection with the merger, which was effective as of September 30, 2004, each common share of EMLR automatically converted into one-twelfth of a common share of our company. In addition, each share of Email Real Estate.com’s outstanding Series B Convertible Preferred Stock automatically converted into approximately 1.41 common shares of our company.

### The Offering

The selling stockholders identified on pages 55-57 of this prospectus are offering on a resale basis a total of 7,340,317 shares:

Common stock offered	7,340,317 shares
Common stock outstanding before the offering <sup>(1)</sup>	17,923,216 shares
Common stock outstanding after the offering <sup>(2)</sup>	17,923,216 shares
Common Stock OTC Bulletin Board symbol	HNAB.OB

(1) Based on the number of shares outstanding as of April 29, 2005, not including approximately 4,035,671 shares issuable upon exercise of various warrants and options to purchase common stock.

Reflects the conversion of our Series A Preferred Stock. In accordance with the terms of the Series A Preferred Stock, all of our  
(2) outstanding shares of Series A Preferred Stock automatically converted into an aggregate of 3,377,409 common shares on January 18, 2005.

## RISK FACTORS

*An investment in our common stock is very risky. You may lose the entire amount of your investment. Prior to making an investment decision, you should carefully review this entire prospectus and consider the following risk factors:*

### **Risks Related to Our Securities**

***Trading of our common stock is limited, which may make it difficult for you to sell your shares at times and prices that you feel are appropriate.***

Trading of our common stock, which is conducted on the National Association of Securities Dealers' Over-the-Counter Bulletin Board (or "OTC Bulletin Board"), has been extremely limited. This adversely affects the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

***Because it may be a "penny stock," it will be more difficult for you to sell shares of our common stock.***

In addition, our common stock is considered a "penny stock" under SEC rules because it has been trading on the OTC Bulletin Board at a price lower than \$5.00. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. Broker-dealers also must provide customers that hold penny stocks in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to you in violation of the penny stock rules, you may be able to cancel your purchase and get your money back. The penny stock rules may make it difficult for you to sell your shares of our stock, however, and because of the rules, there is less trading in penny stocks. Also, many brokers simply choose not to participate in penny-stock transactions. Accordingly, you may not always be able to resell shares of our common stock publicly at times and prices that you feel are appropriate.

***A significant number of shares of our common stock will become available for sale and their sale could depress the price of our common stock.***

Prior to January 18, 2005, we had outstanding approximately 10,793,000 shares of our common stock outstanding, of which only approximately 360,000 shares were available for sale. Because the registration statement relating to this prospectus has been declared effective, all of the shares being offered hereby are now available for sale. In addition, although we have no current plans to do so, we may also sell a substantial number of additional shares of our common stock in connection with a private placement or public offering of our shares of common stock (or other series or class of capital stock to be designated in the future). The terms of any such private placement would likely require us to register the resale of any common shares issued or issuable in the transaction. Further, over the next 12 months, portions of various outstanding options to purchase shares of our common stock that we have issued to employees will begin vesting, meaning those employees will have the right to exercise their right to purchase shares of our stock, often at prices that are substantially less than our current market price. Approximately 417,000 shares will become purchasable under such options in the next 12 months. We may also issue additional shares in connection with our business and may grant additional stock options to our employees, officers, directors and consultants or warrants to third parties. Sales of a substantial number of shares of our common stock in the public market after this offering could adversely affect the market price for our common stock and make it more difficult for you to sell our shares at times and prices that you feel are appropriate.



***Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.***

Since the completion of the EMLR - Hana Biosciences merger transaction in July 2004 through March 21, 2005, the market price of our common stock has ranged from a high of \$15.00 per share to a low of \$1.80 per share, as adjusted to reflect the 1-for-12 combination effected in connection with our September 30, 2004 reincorporation. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

***Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.***

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our shares in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

## **Risks Related to Our Business**

***We currently have no product revenues and will need to raise additional capital to operate our business.***

To date, we have generated no product revenues. Until we receive approval from the U.S. Federal Drug Administration, or “FDA,” and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants. We will need additional financing in addition to such funds, which may not be available on favorable terms, if at all. Given the current and desired pace of clinical development of our three product candidates over the next 12 months, we estimate that we have sufficient capital to fund our research and development activities through 2005. However, we will need to raise additional capital in 2006, likely by selling shares of our capital stock or other securities, in order to fund our research and development activities beyond 2005. There can be no assurance that such capital will be available to us on favorable terms or at all. If we are unable to raise additional funds in the future on acceptable terms, or at all, we may be forced to curtail our desired development activities. In addition, we could be forced to delay or discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the sale of our equity securities, which will have a dilutive effect on our stockholders.

***We are not currently profitable and may never become profitable.***

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the year ended December 31, 2004 we had a net loss of \$7,329,832 and since our inception in December 2002 through December 31, 2004, we have incurred a net loss of \$8,026,158. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable.

Our current “burn rate” - i.e., the amount of cash we spend to fund our operations - is approximately \$900,000 per month. We expect our burn rate to increase substantially in the foreseeable future as we:

- continue to undertake pre-clinical development and clinical trials for our current and new product candidates;
- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- seek to acquire additional technologies to develop; and
- hire additional personnel.

We expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our stock.

***We have a limited operating history upon which to base an investment decision.***

We are a development-stage company that was founded in December 2002. We only have three product candidates, one of which, IPdR, we only acquired the rights to in February 2004, and another, ondansetron lingual spray, we acquired in October 2004. To date, we have not demonstrated an ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technologies and undertaking, through third parties, pre-clinical trials and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

***If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates, we will not be able to market and sell our product candidates.***

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a New Drug Application, or NDA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. Historically, only approximately 11 percent of all drug candidates that start clinical trials are eventually approved for sale. After clinical trials are completed, the FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

***Our product candidates are in early stages of clinical trials, which are very expensive, time-consuming and difficult to design. We cannot predict with any certainty that we will ever receive regulatory approval to sell our product candidates.***

Our product candidates are in early stages of development and require extensive clinical testing. In 2003, the FDA accepted our Investigational New Drug application, or “IND,” for PT-523 and in March 2004 we initiated a Phase I clinical trial at Dana-Farber Cancer Institute, Massachusetts General Hospital and Beth-Israel Deaconess Hospital. We have also recently commenced an open-label multicenter, multinational Phase I and II study of PT-523 in the treatment of relapsed or refractory non-small cell lung cancer (NSCLC). The IND for IPdR is still under development and we may not be in position to commence a Phase I trial until mid to late 2005. We only acquired our rights to OLS in October 2004 and in February 2005 initiated a human clinical study that will compare the pharmacokinetic profile of the lingual spray formulation of ondansetron to the approved oral dosage of Zofran ®. See "Item 1 - Ondansetron Lingual Spray - Clinical and Regulatory Development Plan.”

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Further, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Accordingly, we cannot predict with any certainty when or if we will ever be in a position to submit an NDA for any of our product candidates, or whether any such NDA would ever be approved.

***If the results of our clinical trials do not support our product candidate claims, the completion of development of such product candidates may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.***

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a small patient population. Because of the small sample size, the results of these early clinical trials may not be indicative of future results.

***If physicians and patients do not accept and use our drugs, our ability to generate revenue from sales of our products will be materially impaired.***

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- pharmacological benefit and cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- the price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

***Because we are dependent on clinical research institutions and other contractors for clinical testing and for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.***

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. For example, our current Phase I trial for PT-523 is being conducted by Dana-Farber Cancer Institute, Massachusetts General Hospital and Beth-Israel Deaconess Hospital. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

***Our intention to rely exclusively on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.***

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers, exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we will be ultimately responsible for any of their failures.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

***We have no experience selling, marketing or distributing products and no internal capability to do so.***

We currently have no sales, marketing or distribution capabilities. While we intend to have a role in the commercialization of our products, we do not anticipate having the resources in the foreseeable future to globally develop sales and marketing capabilities for all of our proposed products. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships with other companies having sales, marketing and distribution capabilities, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted at this early stage of our development. There can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.



***If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.***

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. In particular, assuming we obtain approval for PT-523, we will compete with existing antifolate therapies currently being sold by Pfizer (trimetrexate), Eli Lilly & Co. (pemetrexed) and Novartis (edatrexate). Although there are no approved radiation sensitizers currently on the market, there are several product candidates in development that will compete with IPdR and which are significantly further in development. For example, Allos Therapeutics and Pharmacyclics each have a radiation sensitizer in Phase III development. Ondansetron lingual spray will compete with the currently available oral form of the drug, which is currently being manufactured and sold by GlaxoSmithKline under the name Zofran®. These or other future competing products and product candidates may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

***Developments by competitors may render our products or technologies obsolete or non-competitive.***

Companies that currently sell both generic and proprietary compounds for the treatment of cancer include, among others, Pfizer (trimetrexate), Eli Lilly & Co. (pemetrexed), Novartis (edatrexate), and Allos (PDX). Alternative technologies are being developed to treat cancer and immunological disease, several of which are in advanced clinical trials. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.



***If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.***

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We are not aware of any third party infringing on any of our intellectual property rights.

To date, through our license agreements for PT-523, IPdR and ondansetron lingual spray, we hold certain exclusive patent rights, including rights under U.S. patents and U.S. patent applications. We also have patent applications pending in several foreign jurisdictions. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

***If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.***

To date, we have not received any threats, claims or other notices from third parties alleging that our products or methods infringe their rights. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, however, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our product candidates;
- pay damages; or

- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

***Our license agreements relating to our product candidates may be terminated in the event we commit a material breach, the result of which would significantly harm our business prospects.***

Our license agreements relating to PT-523, IPdR and OLS are subject to termination by our licensors in the event we materially breach those agreements. With respect to the PT-523 license, our licensor may terminate the agreement, after giving us notice and an opportunity to cure, if we commit a material breach, including failing to make a scheduled milestone or other payment when due. The agreement also provides that it may be terminated if we become involved in a bankruptcy, insolvency or similar proceeding. Our license agreements for IPdR and OLS contain similar provisions. In the event these license agreements are terminated, we will lose all of our rights to develop and commercialize the applicable product candidate covered by such license, which would significantly harm our business and future prospects. See “Our Company - License Agreements and Intellectual Property - License Agreements.”

***Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.***

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Under recently-proposed legislation, the cost of our product candidates, even if approved for commercial use, may not be reimbursable under Medicare. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

***If we are unable to successfully manage our growth, our business may be harmed.***

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we expect that in the next 12 months we will hire an additional three employees, consisting of one person in an administrative function and two employees focused on research and development. We expect that the total cost of these additional employees will approximate \$325,000 per year. We believe our facilities are sufficient for such additional employees, but additional employees may place a strain on our management by having to address if we are unable to manage our growth effectively, our management business may be harmed. However, we are also actively pursuing additional product candidates to acquire for development. Such additional products, if any, could significantly increase our capital requirements and place further strain on the time on our existing personnel, which may delay or otherwise adversely affect the development of our existing product candidates if our employees do not have the time necessary to devote to developing those products. Alternatively, we may be required to hire even more employees, further increasing the size of our organization and related expenses. If we are unable to manage this growth successfully, we may not efficiently use our resources, which may delay the development of our product candidates.

***We rely on key executive officers and their experience and knowledge of our business would be difficult to replace in the event any of them left our company.***

We are highly dependent on Mark J. Ahn, Ph.D., our president and chief executive officer, Fred Vitale, our vice president-business development, Gregory Berk, our vice president and chief medical officer and Russell Skibsted, our vice president and chief financial officer. Dr. Ahn's, Mr. Vitale's, Dr. Berk's and Mr. Skibsted's employment with us are governed by a written employment agreements. Dr. Ahn's employment agreement provides for a term that expires in November 2006, Mr. Vitale's employment term under his agreement expires in February 2006. Dr. Berk's employment term under his agreement expires in November 2007 and Mr. Skibsted's employment term under his agreement expires in November 2007. Dr. Ahn, Mr. Vitale, Dr. Berk and Mr. Skibsted may terminate their employment with us at any time, however, subject to certain non-compete and non-solicitation covenants. See "Item 10 -Employment Contracts and Termination of Employment and Change of Control Agreements." We are not aware that Dr. Ahn, Mr. Vitale, Dr. Berk and Mr. Skibsted have any plans to leave our company. We do not have "key person" life insurance policies for any of our officers and key employees. The loss of the technical knowledge and management and industry expertise that would resulting the event Dr. Ahn left our company could result in delays in the development of our product candidates and diversion of management resources. The loss of Mr. Vitale could impair our ability to expand our product development pipeline, which may harm our business prospects. The loss of Dr. Berk could impair our ability initiate new, and sustain existing, clinical trials. The loss of Mr. Skibsted could impair our ability to obtain additional financing.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.***

We will need to hire additional qualified personnel with expertise in pre-clinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. In particular, over the next 12 months we will hire an additional three employees, consisting of one person in an administrative function and two employees focused on research and development. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately \$325,000. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the San Francisco Bay Area, is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

***We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.***

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. We currently do not carry product liability insurance but instead maintain a \$5 million clinical trial insurance policy for the ongoing Phase I trials of PT-523. Although we intend to obtain clinical trial insurance prior to the commencement of any clinical trials for IPdR and ondansetron lingual spray, we, or any collaborators, may not be able to obtain insurance at a reasonable cost, if at all. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

#### **NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements contained in this prospectus that are forward-looking in nature are based on the current beliefs of our management as well as assumptions made by and information currently available to management, including statements related to the markets for our products, general trends in our operations or financial results, plans, expectations, estimates and beliefs. In addition, when used in this prospectus, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to us or our management, may identify forward-looking statements. These statements reflect our judgment as of the date of this prospectus with respect to future events, the outcome of which are subject to risks, which may have a significant impact on our business, operating results or financial condition. You are cautioned that these forward-looking statements are

inherently uncertain. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results or outcomes may vary materially from those described herein. The risks identified under the heading “Risk Factors” in this prospectus, among others, may impact forward-looking statements contained in this prospectus.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

### Overview

We are a development stage biopharmaceutical company focused on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. We currently have three product candidates in early-stage development - PT-523, for the treatment of a variety of solid tumor cancers and immunological diseases; IPdR, being developed primarily for the treatment of brain cancers; and ondansetron lingual spray, which is being developed to alleviate chemotherapy-induced nausea and vomiting. To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Since the inception of Hana Biosciences, Inc. in December 2002, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. We are a development stage company and have no product sales to date and we will not receive any product sales until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Developing pharmaceutical products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to complete the development of a product candidate until approximately 2007 or 2008. Currently, a large portion of the development expenses relating to our lead product candidate, PT-523, are being funded by grants. Once the development covered by the grants is complete, we expect that our research and development expenses will increase significantly. In addition, as we initiate development of IPdR and ondansetron lingual spray, our second and third product candidates, respectively, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from various private financings, primarily private sales of our common stock and other equity securities.

Our 2004 highlights include the following product development and business achievements:

- Three oncology products entered the development pipeline.
  - o PT-523, a novel nonpolyglutamable antifolate for non-small cell lung cancer, cervical cancer and acute lymphocytic leukemia, was licensed from Harvard and entered clinical trials. In the first quarter of 2005, we began a Phase I and II clinical trial with our lead compound, PT-523, in non-small cell lung cancer, or "NSCLC," with five sites in the U.S. and ten sites in Russia.
  - o IPdR, a novel radiosensitizer, for pancreatic, colorectal, liver, and brain cancers was licensed from Yale University and The Research Foundation of the State University of New York at Buffalo.
  - o Ondansetron Lingual Spray (OLS) for chemotherapy-induced nausea and vomiting, was licensed from NovaDel, Inc. Ondansetron hydrochloride is the active ingredient of GlaxoSmithKline's Zofran,<sup>®</sup> which in 2003, had sales of about \$1.0 billion. GSK's product patent expires in June, 2006, and OLS is on target to start producing revenues for Hana in 2007. In February 2005, we commenced a pilot pharmacokinetic, or "PK," study with OLS, the results to which we expect by the second quarter of 2005.
- We completed two financings of \$12.7 million and secured research grants totaling \$12 million.



Over the next several months we expect to begin a Phase I with IPdR in pancreatic, liver and colorectal cancer at Case Western and a Phase I and II study with IPdR in Glioblastoma Multiforme at the New Approaches to Brain Tumor Therapy. We also expect to begin Phase I and II trials in acute lymphoblastic leukemia and cervical cancer at M.D. Anderson in Houston, Texas and the Gynecologic Oncology Group, respectively. Later in the year we expect to do a pivotal PK study in healthy volunteers and a Phase IV in adjuvant breast cancer with Ondansetron lingual spray. Phase IV trials look at the long-term safety and benefits of a treatment. It continues to study the treatment once it has been approved for use and doctors are able to give it to patients routinely. Phase IV studies are useful for gathering information on any side effects that may have been missed in the earlier trials.

Our company resulted from the July 2004 merger of EMLR, a Colorado corporation incorporated in March 2001, and Hudson Health Sciences, Inc., a Delaware corporation. In connection with that transaction, a wholly-owned subsidiary of EMLR merged with and into Hudson Health Sciences, with Hudson Health Sciences remaining as the surviving corporation and a wholly-owned subsidiary of EMLR. Hudson Health Sciences changed its name to "Hana Biosciences, Inc." in connection with the merger. In exchange for their shares of capital stock in Hana Biosciences, the former stockholders of Hana Biosciences received shares of capital stock of EMLR representing approximately 87 percent of the outstanding equity of EMLR on a fully-diluted basis after giving effect to the transaction. In addition, the terms of the merger provided that the board of directors of EMLR would be reconstituted immediately following the effective time of the transaction such that the directors of EMLR were replaced by the directors of Hana Biosciences. Further, upon the effective time of the merger, the business of EMLR was abandoned and the business plan of Hana Biosciences was adopted. The transaction was therefore accounted for as a reverse acquisition with Hana Biosciences, Inc. as the acquiring party and EMLR as the acquired party. Accordingly, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of Hana Biosciences, Inc., unless the context indicates otherwise.

Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and organizational affairs and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred.

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees represents the difference between the fair value of our common stock and the exercise price of the options at the date of grant. We account for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation." Compensation for options granted to consultants has been determined in accordance with SFAS No. 123 as the fair value of the equity instruments issued. APB Opinion No. 25 has been applied in accounting for fixed and milestone-based stock options to employees and directors as allowed by SFAS No. 123. We currently have no outstanding milestone-based options. This amount is being recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statement of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.



## Results of Operations

### *Year Ended December 31, 2003 versus Period from December 6, 2002 to December 31, 2002*

*General and administrative expenses.* For the year ended December 31, 2003, general and administrative expense was \$229,601 as compared to \$2,065 for the period from December 6, 2002 to December 31, 2002. The increase of \$227,536 was due primarily to an increase in payroll expenses of approximately \$140,000 which corresponds to our increase in headcount from zero full-time employees at December 31, 2002 to two full-time employees at December 31, 2003. At December 31, 2003, we also recognized an increase in rent and utilities expense of approximately \$10,000 relating to the leasing of new facilities in December 2003. We also incurred additional professional fees of approximately \$42,000 at December 31, 2003 relating to expenses incurred for general business consulting.

*Research and development expenses.* For the year ended December 31, 2003, R&D expense was \$309,376 as compared to \$142,405 for the period from December 6, 2002 to December 31, 2002. The increase of \$166,971 resulted from an increase in professional service expense of approximately \$154,000 incurred as a result of the continued development of PT-523.

*Interest Expense.* For the year ended December 31, 2003, interest expense was \$12,879 as compared to \$0 for the period from December 6, 2002 to December 31, 2002. The increase is a result of an increase in the amount of interest bearing notes payable in 2003 when compared to 2002.

*Net loss.* Net loss for the year ended December 31, 2003 was \$551,856 as compared to \$144,470 for the period from December 6, 2002 to December 31, 2002. This increase in net loss is attributable primarily to an increase in research and development expenses of \$166,971 and an increase in general and administrative expenses of \$227,536.

### *Year Ended December 31, 2004 Compared to Year Ended December 31, 2003*

*General and administrative expenses.* For the year ended December 31, 2004, general and administrative expense was \$2,808,706 as compared to \$229,601 for the year ended December 31, 2003. The increase of \$2,579,105 is due primarily to an increase in payroll expenses of approximately \$826,000 and in increase in employee benefits expense of approximately \$82,000. This increase is a result of our increase in headcount from two full-time employees at December 31, 2003 to four full-time employees at December 31, 2004 in the general and administrative department. Another factor contributing to the overall increase in general and administrative expenses was an increase in rent and utilities expense of approximately \$140,000. This increase was a result of relocating our corporate headquarters from New York to California and the corresponding leasing of new facilities with rent expense totaling approximately \$10,000 per month. For the year ended December 31, 2004, we recognized an increase in professional fees and travel expense of approximately \$700,000 and \$213,000, respectively, when compared to the year ended December 31, 2003. The increase in professional fees primarily relates to legal and accounting expenses incurred for the July 2004 merger and the resulting public reporting under federal securities laws. Another contributing factor to the increase in professional fees was the newly hired investor relations firm. The increase in travel expense for the year ended December 31, 2004 relates to executive travel in connection with investor meetings. Other increases for the year ended December 31, 2004 when compared to the corresponding period of the previous year is an increase in depreciation of \$16,000 and an increase in director and officer insurance of \$49,000. For the year ended December 31, 2004, we also incurred stock-based compensation expense for options issued to employees totaling approximately \$263,000, no corresponding expense existed for the year ended December 31, 2003. In addition, for the year ended December 31, 2004 we incurred stock-based compensation expense of approximately \$169,000 relating to common stock to be issued in 2005, no corresponding expense existed for the year ended December 31, 2003.

*Research and development expenses.* For the year ended December 31, 2004, research and development (“R&D”) expense was \$4,546,519 as compared to \$309,376 for the year ended December 31, 2003. The increase of \$4,237,143 is due primarily to an increase in salaries of \$775,000 which resulted from increasing our full-time employees from none at December 31, 2004 to nine full-time employees devoted to R&D at December 31, 2004. For the year ended December 31, 2004, we incurred an expense of \$200,000 associated with milestone payments related to advancements in PT-523 and IPdR. No such expense existed for the year ended December 31, 2003. For the year ended December 31, 2004, we also recognized an expense of \$500,000 related to the issuance of common stock to NovaDel, Inc. in partial consideration for the license agreement signed in 2004. In addition, pursuant to the terms of the NovaDel, Inc. license agreement, in exchange for \$1,000,000, we purchased 400,000 shares of the NovaDel’s common stock at a per share price of \$2.50, a premium of \$0.91 per share or \$364,000 over the then market value of our common stock. This \$364,000 was expensed as part of the license fee in the year ended December 31, 2004. We also recognized an increase in professional outside services of \$1,683,000. This increase relates to the continuing development of our three lead compounds (PT-523, IPdR and OLS) and includes costs incurred for the physical manufacturing of drug compounds, payments to our contract research organization and legal expenses associated with our continued patent protection. Other increases for the year ended December 31, 2004 when compared to the corresponding period of the previous year is an increase in clinical trial insurance of \$24,000 and an increase in travel expense of \$101,000. For the year ended December 31, 2004 we also incurred stock-based compensation expense for options issued to employees totaling approximately \$113,000, no corresponding expense existed for the year ended December 31, 2003. In addition, for the year ended December 31, 2004 we incurred stock-based compensation expense of approximately \$81,000 relating to common stock to be issued in 2005, no corresponding expense existed for the year ended December 31, 2003. For the year ended December 31, 2004 we incurred expense of approximately \$302,000 relating to the fair value option grants to non employees for services rendered for the year ended December 31, 2004. No such expense was present in the corresponding period of 2003. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that we will need approximately \$8.8 million in order to fund our research and development activities. This amount includes milestone payments that we expect to be triggered under the license agreements relating to our product candidates, the manufacturing and clinical trial costs for our three product candidates and the salaries associated with those individuals in the research and development department. Because we do not currently have sufficient cash on hand to satisfy our R&D capital requirements for the next 12 months, we will need to raise additional capital in 2005, likely by selling shares of our capital stock or other securities. We currently have no specific plans to raise such additional capital and there can be no assurance that such capital will be available to us on favorable terms or at all. In the event we are not able to raise additional capital in 2005, we will be forced to curtail our planned R&D activities for 2005, which will delay the overall development of our product candidates. See “ - Liquidity and Capital Resources.”

*Interest income (expense), net.* For the year ended December 31, 2004, net interest income was \$26,040 as compared to net interest expense of \$12,879 for the year ended December 31, 2003. The increase of \$38,919 resulted from our increased cash balance deposited in interest earning money market accounts as well as our repayment of all notes payable during the current year.

*Other income (expense), net.* For the year ended December 31, 2004, net other expense was \$647 as compared to zero for the corresponding period of 2003. The increase is attributed to our miscellaneous minimum state tax payments offset by dividend income received from a cash account not present in 2003.

*Net loss.* Net loss for the year ended December 31, 2004 was \$7,329,832 as compared to \$551,856 for the year ended December 31, 2003. This increase in net loss is attributable primarily to an increase in research and development expenses of \$4,237,143 and an increase in general and administrative expenses of \$2,579,105.

## **Liquidity and Capital Resources**

From inception to December 31, 2004, we have incurred an aggregate net loss of \$8,026,158, primarily as a result of expenses incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity and debt financing. From inception through December 31, 2004, we had a net increase in cash and cash equivalents of \$6,584,361. This increase primarily resulted from net cash provided by financing activities of \$12,533,155, substantially all of which was derived from our two private placements which netted us \$12,379,155. The increase in cash provided by financing activities was offset by net cash used in operating activities of \$5,177,164 and net cash used in investing activities of \$771,630 for the cumulative period from inception to December 31, 2004.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through December 31, 2004, a significant portion of our financing has been through private placements of common stock, preferred stock and debt financing. We will continue to fund operations from cash on hand and through future placements of capital stock or debt financings. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Although we expect to have sufficient cash to fund our operations through 2005, this would require a significant reduction in the pace of our three ongoing clinical trials. Given the current and desired pace of clinical development of our three product candidates, we estimate that we will need to raise additional capital in 2005 in order to fund our development activities over the next 12 months, likely by selling shares of our capital stock or other securities, in order to fund our research and development activities. If we are unable to raise additional capital in 2005, we will likely be forced to curtail our desired development activities over the next 12 months, which will delay the development of our product candidates. There can be no assurance that such capital will be available to us on favorable terms or at all. We will need additional financing thereafter until we can achieve profitability, if ever.

**Financings.** In February 2004, we raised gross proceeds of approximately \$4.7 million through the sale of 2,802,989 shares of our common stock. In connection with this offering, we paid commissions and other offering-related expenses consisting of \$341,979 in cash and issued a 5-year warrant to purchase 277,331 shares of our common stock to Paramount BioCapital, Inc., as placement agent services rendered.

Immediately prior to the EMLR - Hana Biosciences merger in July 2004, we raised gross proceeds of \$8 million through the sale of 2,395,210 shares of Series A Convertible Preferred Stock. Each share of Series A Convertible Preferred Stock is convertible at the holder's election into 1.410068 common shares. On January 18, 2005, the effective date of the registration statement covering the resale of the common shares issuable upon conversion of the Series A Preferred Stock, the Series A Preferred Stock automatically converted into 3,377,409 shares of common stock.

In April 2004, we raised gross proceeds of approximately \$4.93 million through the sale of 3,849,472 shares of our common stock at a price of \$1.28 per share. In connection with this offering, we also issued to the investors five-year warrants to purchase an aggregate of 1,154,826 shares of common stock at a price of \$1.57 per share. We also paid commissions and other offering related expenses of approximately 315,000 and issued to placement agents 5-year warrants to purchase an aggregate of 344,159 shares at a price of \$1.57 per share.



***Current and Future Financing Needs.*** We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that we will need approximately \$8.8 million in order to fund our research and development activities. This amount includes 6.0 million relating to milestone payments that we expect to be triggered under the license agreements relating to our product candidates and the manufacturing and clinical trial costs for our three product candidates. The remaining amount is devoted to salaries associated with those individuals in the research and development department. Because we do not currently have sufficient cash on hand to satisfy our R&D capital requirements for the next 12 months, we will need to raise additional capital in 2006, likely by selling shares of our capital stock or other securities. We currently have no specific plans to raise such additional capital and there can be no assurance that such capital will be available to us on favorable terms or at all. In the event we are not able to raise additional capital in 2006, we will be forced to curtail our planned R&D activities for 2006, which will delay the overall development of our product candidates.

However, the actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our stock or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

## ***Plan of Operation***

Our plan of operation for the year ending December 31, 2005 is to continue implementing our business strategy, including the clinical development of our three product candidates. We also intend to expand our drug candidate portfolio by acquiring additional drug technologies for development. We expect our principal expenditures during the next 12 months to include:

- operating expenses, including expanded research and development and general and administrative expenses; and
- product development expenses, including the costs incurred with respect to applications to conduct clinical trials in the United States for PT-523, IPdR and ondansetron lingual spray.

As part of our planned expansion, we anticipate hiring 3 additional full-time employees, all of whom will be devoted to research and development activities. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing. As indicated above, at our current and desired pace of clinical development of our three product candidates, over the next 12 months we expect to spend approximately \$8.8 million on clinical development (including milestone payments that we expect to be triggered under the license agreements relating to our product candidates), \$1.8 million on general corporate, and \$120,000 on facilities rent. We expect to have completed our Phase I trial for PT-523 and to have initiated our Phase I trial for IPdR. Additionally, we expect to have initiated clinical trials for ondansetron lingual spray.

## ***Research and Development Projects***

**PT-523.** In 2003, we submitted an Investigational New Drug application (“IND”) with the U.S. Food and Drug Administration (“FDA”) to commence Phase I clinical trials of PT-523 for the treatment of cancer. Phase I trials, which commenced in April 2004, will involve an estimated 20 - 45 patients, to date twelve patients have received doses of PT-523. The primary purposes for this study are to evaluate the safety of PT-523 when administered intravenously to patients with solid tumors and who have failed curative or survival prolonging therapy or for whom no such therapies exist, establish the maximum tolerated dose, and identify dose limiting toxicities. In 2005, we plan to initiate a Phase I/II study in previously treated non-small cell lung cancer, a Phase I/II trial in recurrent Acute Lymphocytic Leukemia (“ALL”) and a Phase II trial in recurrent cervical cancer.

PT-523 has received clinical development grants from the National Cancer Institute covering approximately \$8 million in development activities. These grants cover the predominant cost of pre-clinical efficacy and safety testing, clinical manufacturing, and Phase I clinical program. Under the terms of these grants, all amounts are disbursed directly to the institutions conducting the studies. None of the funds are disbursed to us and we have no obligation to repay such funds. We estimate that the NCI has disbursed approximately \$1 million in connection with the development of PT-523. Through fiscal 2004, we have incurred \$1,300,052 of costs related to our development of PT-523, of which \$272,205 was incurred in fiscal 2003, and \$1,027,847 was incurred in 2004. Currently, we anticipate that we will need to expend approximately an additional \$1,200,000 to \$1,500,000 in development costs in fiscal 2005 and at least an aggregate of approximately \$75 million until we receive FDA approval for PT-523, should we opt to continue development. Costs incurred are a direct result of ensuring proper study conduct in accordance with local regulations. Should we choose to continue development we expect that it will take an additional 4-5 years before we complete development and obtain FDA approval of PT-523, if ever.

We believe we currently have sufficient capital to fund development activities of PT-523 during the remainder of 2004 and 2005. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2005. We expect to raise such additional capital by either borrowing money or by selling shares of our capital stock. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to PT-523 or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business. Further, our assumptions relating the expected costs of development and timeframe for completion are dependent on numerous factors other than available financing, including unforeseen safety issues, lack of effectiveness, and significant unforeseen delays in the clinical trial and regulatory approval process, any of which could be extremely costly. In addition, our estimates assume that we will be able to enroll a sufficient number of patients in each clinical trial.

**IPdR.** In August 2004, an investigator-initiated IND was submitted to the FDA to initiate a Phase I clinical trial of IPdR for the treatment of selected radiosensitive cancers. Assuming FDA approval of the IND, a phase I trial is expected to commence by mid to late 2005, which we estimate will involve approximately 40-60 patients. The primary purposes for this study will be to evaluate the safety of oral IPdR in patients with selected radiosensitive and who have failed curative or survival prolonging therapy or for whom no such therapies exist, establish the maximum tolerated dose, and identify dose limiting toxicities. In addition, we expect to commence a clinical trial in glioblastoma multiforme, a type of brain cancer, in 2005.

IPdR has received clinical development grants from the National Cancer Institute. These grants cover the predominant cost of pre-clinical efficacy and safety testing, clinical manufacturing, and Phase I clinical program. Under our license agreement the Company was obligated to reimburse other parties approximately \$15,000 for past patent expenses. Since acquiring our rights to IPdR, through December 31, 2004, we have incurred \$656,251 of project costs related to our development of that product candidate, all in fiscal 2004. Currently, we anticipate that we will need to expend an additional \$500,000 to \$1,000,000 in development costs in fiscal 2005 and at least an aggregate of approximately \$50 million until we receive FDA approval for IPdR, should we opt to continue development. Should we choose to continue, we expect that it will take an additional 5 or 6 years until we will have completed development and obtained FDA approval of IPdR, if ever.

We believe we currently have sufficient capital to fund our development activities of IPdR during 2005. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2005. We expect to raise such additional capital by either borrowing money or by selling shares of our capital stock. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to IPdR or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business. In addition to the risks presented in the event we are unable to raise sufficient capital to fund development of IPdR, our assumptions regarding the costs and timeframe for development of IPdR assume that no unforeseen safety or efficacy issues arise, that we are able to achieve sufficient levels of patient enrollment in the clinical trials, and that no significant unforeseen delays in the clinical trial and regulatory approval process arise. If any of these assumptions prove to be incorrect or any of these risks materialize, our development costs could significantly increase and the timing of our development could be significantly delayed, either of which could make development more costly or jeopardize the completion of IPdR development altogether. See also the risks identified under the section entitled “Risk Factors” following Item 1 in this Annual Report.

**Ondansetron Lingual Spray.** In October 2004, we acquired the exclusive license rights to develop and commercialize ondansetron lingual spray, or “OLS,” in the United States and Canada. As initial consideration for that license, we purchased 400,000 shares of common stock of NovaDel Pharma, Inc., our licensor, for an aggregate price of \$1 million, and we issued to NovaDel 73,121 shares of our common stock. Other than our purchase of NovaDel shares and the issuance to NovaDel of our shares, we have not yet expended any significant funds toward development of OLS. NovaDel is undertaking to complete, at its expense, an initial pharmacokinetic, or “PK,” study with respect to OLS in the first half of 2005. PK studies measure the degree to which a drug is absorbed, distributed, metabolized and eliminated by the body. Until we receive the results of the PK study, however, we will not be able to formulate a development plan for OLS and, therefore, cannot provide any reasonable assessment of the overall anticipated scope, timing and cost of completing development of OLS.

## Off-Balance Sheet Arrangements

**License Agreements.** In the event we achieve certain milestones in connection with the development of our product candidates, we will be obligated to make milestone payments to our licensors in accordance with the terms of our license agreements, as discussed below. The development of pharmaceutical product candidates is subject to numerous risks and uncertainties, including, without limitation, the following: (1) risk of delays in or discontinuation of development from lack of financing, (2) our inability to obtain necessary regulatory approvals to market the products, (3) unforeseen safety issues relating to the products, (4) our ability to enroll a sufficient number of patients in our clinical trials, and (5) dependence on third party collaborators to conduct research and development of the products. Additionally, on a historical basis, only approximately 11 percent of all product candidates that enter human clinical trials are eventually approved for sale. Accordingly, we cannot state that it is reasonably likely that we will be obligated to make any milestone payments under our license agreements. Summarized below are our future commitments under our license agreements, as well as the amounts we have paid to date under such agreements.

*PT-523 License.* Our rights to PT-523 are governed by the terms of a December 2002 license agreement with Dana-Farber Cancer Institute and Ash Stevens, Inc. The agreement provides us with an exclusive worldwide royalty bearing license, including the right to grant sublicenses, to the intellectual property rights and know-how relating to PT-523 and all of its uses. Upon execution of the license agreement, we paid a \$100,000 license fee and reimbursed our licensors for approximately \$11,000 of patent-related expenses. The license agreement also requires us to make an annual license fee payment of \$25,000 and provides for future payments totaling up to \$6 million upon the achievement of certain milestones, including a \$5 million payment upon approval by the FDA of a New Drug Application for PT-523. To date, we have made one of these milestone payments in the amount of \$100,000 following commencement of the Phase I clinical trial. Additionally, we are obligated to pay royalties in the amount of 3.5 percent of “net sales” (as defined in the license agreement) of PT-523. We are also required to pay to the licensors 20 percent of fees or non-royalty consideration (e.g., milestone payments, license fees) received by us in connection with any sublicense of PT-523 granted prior to the start of a Phase II trial, and 15 percent of such fees after initiation of a Phase II clinical trial. See “Item 1 - License Agreements - IPdR License.”

*IPdR License.* In February 2004, we entered into an exclusive worldwide, royalty-bearing license agreement with Yale University and The Research Foundation of State University of New York, including the right to grant sublicenses, for the rights to the intellectual property relating to IPdR. The license agreement expires as the patent rights subject to the license expire. The IPdR license covers two issued patents, expiring in 2007 and 2015, respectively. In addition to a \$100,000 license fee paid on execution of the agreement, we are required to make additional license payments in the aggregate amount of \$500,000 upon the completion of a Phase IIb clinical trial (currently estimated to be during fiscal 2006) and upon NDA approval by the FDA, which we estimate to occur no earlier than 2010, if ever. As further consideration for the license, we are required to pay royalties to Yale and SUNY equal to 3 percent of net sales (as defined in the license agreement) from IPdR. See “Item 1 - License Agreements - IPdR License.”



*OLS License.* Our rights to OLS are subject to the terms of an October 2004 license agreement with NovaDel Pharma, Inc. The license agreement grants us a royalty-bearing, exclusive right and license to develop and commercialize OLS within the United States and Canada. The technology licensed to us under the license agreement currently covers one United States issued patent, which expires in March 2022. In consideration for the license, we issued 73,121 shares of our common stock to NovaDel and have agreed to make double-digit royalty payments to NovaDel based on a percentage of “net sales” (as defined in the agreement). We are also obligated to make various milestone payments in an aggregate amount of up to \$10 million. In addition, we purchased from NovaDel 400,000 shares of its common stock at a price of \$2.50 per share for an aggregate payment of \$1 million. See “Item 1 - License Agreements - OLS License.”

*Lease Agreements.* In December 2004 the Company entered into an office lease that expires on December 31, 2005. Total lease commitments under this lease amount to approximately \$121,000.

*Employment Agreements.* The Company entered into a written three year employment agreement with its President and Chief Executive Officer dated November 1, 2003. The aggregate amount of compensation to be provided for over the remaining term of the agreement amounted to approximately \$458,000 at December 31, 2004.

The Company entered into a written two year employment agreement with its Vice President of Business Development on January 25, 2004. The aggregate amount of compensation to be provided for over the remaining term of the agreement amounted to approximately \$175,000 at December 31, 2004.

The Company entered into a written three year employment agreement with its Vice President and Chief Medical Officer on October 21, 2004. The aggregate amount of compensation to be provided for over the remaining term of the agreement amounted to approximately \$425,000 at December 31, 2004.

The Company entered into a written three year employment agreement with its Vice President and Chief Financial Officer on November 15, 2004. The aggregate amount of compensation to be provided for over the remaining term of the agreement amounted to approximately \$511,000 at December 31, 2004.

### **Critical Accounting Policies**

In December 2001, the SEC requested that all registrants discuss their most “critical accounting policies” in management’s discussion and analysis of financial condition and results of operations. The SEC indicated that a “critical accounting policy” is one which is both important to the portrayal of the company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

## **Research and Development Expenses**

Research and development expenses are expensed as incurred.

## **Stock-Based Compensation**

Options, warrants and stock awards issued to non-employees and consultants are recorded at their fair value as determined in accordance with Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," and EITF No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and recognized as expense over the related vesting period.

Options issued to employees have been accounted for using the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees," which only required charges to compensation expense for the excess, if any, of the fair value of the underlying stock at the date the stock option is granted (or at an appropriate subsequent measurement date) over the amount the employee must pay to acquire the stock.

## **Recently Issued Accounting Standards**

In December 2004, the FASB issued SFAS No. 123 (R), "Share-Based Payment." SFAS 123 (R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services and focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS 123 (R) requires that the fair value of all such equity instruments, including employee stock options, be recognized as expense in the historical financial statements as services are performed. Prior to SFAS 123 (R), only certain pro forma disclosures of fair value were required. SFAS 123 (R) shall be effective for small business issuers as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. The adoption of SFAS 123 (R) will require us to record charges for all employee stock options and is expected to have a material impact on the financial statements of Hana Biosciences during the calendar year 2006.

The FASB and the Accounting Standards Executive Committee of the American Institute of Certified Public Accountants had issued certain other accounting pronouncements as of December 31, 2004 that will become effective in subsequent periods; however, management of the Company does not believe that any of those pronouncements would have significantly affected the Company's financial accounting measurements or disclosures had they been in effect during 2004 or 2003.

## OUR COMPANY

### Overview

We are a development stage biopharmaceutical company focused on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. We currently have three product candidates in early-stage development - PT-523, for the treatment of a variety of solid tumor cancers; IPdR, being developed primarily for the treatment of brain cancers; and ondansetron lingual spray, which is being developed to alleviate chemotherapy-induced nausea and vomiting. To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Our executive offices are located at 400 Oyster Point Boulevard, Suite 215, South San Francisco, California 94080. Our telephone number is (650) 588-6404 and our Internet address is [www.hanabiosciences.com](http://www.hanabiosciences.com).

### Strategic Focus

We are committed to creating value by building a world-class team, accelerating the development of lead product candidates and expanding our pipeline by being the alliance partner of choice.

- **People: Building a world-class team and leading core competencies in clinical, regulatory, business development, and commercialization.** Our management and advisors are comprised of experienced biotechnology and pharmaceutical industry entrepreneurs and respected experts in the field of oncology and immunology.

- **Product Candidates: Accelerating the development of our three lead product candidates, PT-523, IPdR, and Ondansetron Lingual Spray (OLS).** PT-523 is a novel non-classical antifolate that is a water-soluble, nonpolyglutamatable analogue of aminopterin discovered at the Dana-Farber Cancer Institute and the National Cancer Institute. IPdR is a novel orally administered prodrug for IUdR discovered at Yale University which is being developed as a radiosensitizer in various tumors including brain cancers. **Ondansetron Lingual Spray (OLS)** is a novel delivery system that utilizes the vast and highly-absorptive surfaces of the oral mucosa to deliver ondansetron directly into the bloodstream and achieve therapeutic levels in a shorter period of time compared to conventional oral dosage forms. We have exclusive license rights to develop and commercialize all three product candidates.

- **Pipeline: Expanding our pipeline by being the partner of choice for suppliers, researchers, and alliance partners.** As a key component of our strategy, we seek to acquire global rights to additional product candidates and form alliances in oncology and immunology, while continuing to develop and commercialize new products and line extensions.

### Historical Development; Merger Transaction

We were incorporated under Delaware law in December 2002 under the name Hudson Health Sciences, Inc. In July 2004, we acquired publicly-held Email Real Estate.com, Inc. (“EMLR”), a Denver, Colorado based company that had been formed for the purpose of developing Internet web sites for the real estate industry, in a reverse merger transaction. In connection with the transaction, a wholly-owned subsidiary of EMLR merged into our company, with us remaining as a wholly-owned subsidiary of EMLR. In connection with the merger, EMLR issued to our stockholders approximately 85 percent of its outstanding equity. In addition, our management replaced the management of EMLR and the combined company adopted our business plan. Accordingly, for accounting purposes, the transaction was treated as a reverse acquisition with Hana Biosciences as the accounting acquirer (legal acquiree) and EMLR as the accounting acquiree (legal acquirer).

In September 2004, EMLR was reincorporated under Delaware law. The reincorporation, approved by the shareholders at a special meeting held September 29, 2004, was accomplished by merging EMLR into Hana Biosciences, then its wholly-owned subsidiary, with Hana remaining as the surviving corporation. In connection with the reincorporation, each share of the company's outstanding common stock became automatically exchangeable into one-twelfth of a common share of the reincorporated company.

## **Cancer Overview**

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 can arise in any organ of the body and, according to the American Cancer Society, strikes one of every two American men and one of every three American women at some point in their lives.

The American Cancer Society estimates that nearly 1.4 million new cases of cancer are diagnosed in the United States, a figure that does not include the 1 million cases of skin cancer diagnosed annually. Cancer is the second leading cause of death (after heart disease) in the United States, expected to account for about 570,280 deaths in 2005.

There are more than 100 different varieties of cancer, which can be divided into six major categories. Carcinomas, the most common type of cancer, originate in tissues that cover a surface or line a cavity of the body. Sarcomas begin in tissue that connects, supports or surrounds other tissues and organs. Lymphomas are cancers of the lymph system, the circulatory system that bathes and cleanses the body's cells. Leukemias involve blood-forming tissues and blood cells. As their name indicates, brain tumors are cancers that begin in the brain, and skin cancers, including dangerous melanomas, originate in the skin. Cancers are considered metastatic if they spread via the blood or lymphatic system to other parts of the body to form secondary 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.

In 2004, one in four deaths in the US is expected to be due to cancer. For all forms of cancer combined, the 5-year relative survival rate is 64%. 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. 1997 was the first year in the past half century in which fewer Americans died of cancer than the year before—the start of what researchers hope will be a long-term decline in cancer deaths.

The cost of cancer to the healthcare system is significant. The National Institute of Health 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.

In addition, according to Reuters Business Institute, the global cancer market is estimated at \$33.5 billion in 2003. Cytotoxics or antineoplastics account for 28 percent or \$9.5 billion of the total global cancer drug market. Predominant classes of cytotoxic agents are antimetabolites, alkylating agents, cytotoxic antibiotics, vinca alkaloids, platinum compounds, and taxanes.

## Cancer Treatments

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. There are also many experimental treatments under investigation including radiation sensitizers, vaccines, gene therapy and immunotoxins.

**Cytotoxics.** Cytotoxics are anticancer drugs that destroy cancer cells by stopping them from multiplying. Healthy cells can also be harmed with the use of cytotoxics, especially those that divide quickly. Harm to healthy cells is what causes side effects. These cells usually repair themselves after chemotherapy. Chemotherapy can be used for different purposes which include curing cancer (when the patient remains free of evidence of cancer cells), controlling cancer (by preventing the cancer from spreading), and to relieving symptoms of cancer (such as pain, helping patients live more comfortably).

Cytotoxic agents act primarily on macromolecular synthesis, repair or activity, which affects the production or function of DNA, RNA or protein. For example, our drug candidate PT-523 is a novel non-classical antifolate or antimetabolite that is a cytotoxic agent for the treatment of solid tumors. 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 antitumor activity by the drug, but instead the result of empirical clinical trials.

**Radiotherapy.** Also called radiation therapy, radiotherapy 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).

Scientists are also looking for ways to increase the effectiveness of radiation therapy. Two types of investigational drugs are being studied for their effect on cells exposed to radiation. Radiosensitizers, such as IPdR being developed by Hana Biosciences, increase the damage done to tumor cells by radiation; and radioprotectors protect normal tissues from the effects of radiation.

**Supportive care.** 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.

Side effects, or complications, of treatment cause inconvenience, discomfort, and occasionally, may even be fatal. Additionally and perhaps more importantly, side effects may also prevent doctors from delivering the prescribed dose of therapy at the specific time and schedule of the treatment plan. Therefore, side effects 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.

In addition to anemia, fatigue, hair-loss, reduction in blood platelets and white and red blood cells, and bone pain, one of the most common side effects of chemotherapy is nausea and vomiting. Several drugs have been developed to help prevent and control chemotherapy-induced nausea and vomiting, which have led to improvements in the management of symptoms associated with this cancer treatment, allowing for greater accuracy and consistency concerning the administration of cancer treatment. Nausea and vomiting induced by chemotherapy are treated by drugs such as 5-HT<sub>3</sub> receptor antagonists, like ondansetron lingual spray being developed by Hana Biosciences, which are selective blocking agents of the hormone serotonin.

## Overview

We obtained a license to develop and commercialize PT-523, our lead product candidate, from the Dana-Farber Cancer Institute and Ash Stevens, Inc. in December 2002. PT-523 is a cytotoxic agent that we are developing for the treatment of various solid tumors. PT-523 is currently in a Phase I clinical trial being conducted at Dana-Farber, Massachusetts General Hospital and Beth-Israel Deaconess Hospital and a multicenter Phase I and II study in patients with relapsed or refractory non-small cell lung cancer or “NSCLC”.

## Product Description

PT-523 is a novel, non-classical antifolate that was developed at Dana-Farber and the National Cancer Institute as part of a program to identify products with improved efficacy, tolerability and decreased resistance. Antifolates are an important class of cytotoxic or antineoplastic agents (substances that inhibit the growth of tumors) which are antimetabolites (substances that disrupt the metabolic process). Antifolates, and methotrexate specifically, have been used clinically for more than 30 years to treat both solid and hematological cancers (such as breast cancer and acute lymphocytic leukemia), as well as inflammatory diseases (such as rheumatoid arthritis). Antimetabolites in this product class, such as methotrexate, are structurally related to folic acid and act as antagonists to this vitamin by inhibiting the enzyme that converts folic acid to its active form. Rapidly dividing cells, such as cancer cells, need folic acid to multiply. The decreased level of folic acid leads to depressed DNA, RNA, and protein synthesis which in turn leads to cell death.

Antifolates are an important class of cytotoxic agents, which are antimetabolites, or drugs that are structurally similar to naturally occurring metabolites, but differ enough to interfere with normal metabolic pathways. Antifolates, also known as folic acid analogs, have been used clinically for more than 30 years to treat both solid and hematological cancers (such as breast cancer and acute lymphocytic leukemia), as well as inflammatory diseases (such as rheumatoid arthritis). Antimetabolites, such as methotrexate, are structurally related to folic acid and act as antagonists to this vitamin by inhibiting the enzyme that converts folic acid to its active form. Rapidly dividing cells, such as cancer cells, need folic acid to multiply. The decreased level of this active vitamin leads to depressed DNA, RNA, and protein synthesis which in turn lead to apoptosis, or cell death.

The combined results of several preclinical studies suggest that PT-523 has the potential to significantly enhance the treatment of patients with cancer and other autoimmune diseases. Potential advantages of PT-523 over existing therapies include increased potency and a superior resistance profile.

- *Increased potency:* PT-523 is cytotoxic because it inhibits dihydrofolate reductase, or “DHFR,” an enzyme involved in the biosynthesis of folic acid coenzymes. PT-523 is more tightly bound to DHFR and enters cells more efficiently through the reduced folate carrier transport system pathway than other antifolates, including methotrexate. These properties of PT-523 result in its increased potency in the inhibition of tumor cell growth.

- *Superior resistance profile:* Classic antifolates, such as methotrexate, need to be polyglutamated for intracellular retention and effective inhibition of targeted enzymes. Cancer cells are either intrinsically resistant, or develop resistance to, methotrexate. By replacing the glutamic side chain in methotrexate, PT-523 does not require polyglutamation for its activity and therefore circumvents drug resistance due to the defect in polyglutamation. In preclinical studies, PT-523 has demonstrated efficacy against tumor cells that were resistant to other antifolates.

*Better Tolerability:* Classical compounds such as methotrexate are polyglutamated once they enter the cells. This polyglutamation allows the drug to stay in the cell and act on its target more effectively. However, while healthy cells maintain their ability to make polyglutamates, cancer cells lose their ability to form polyglutamates. Consequently, the drug stays in the healthy cells, causing toxicity, but it is not able to exert its effect on the cancer cell to kill it. PT-523 solves this problem by blocking and altering the side chain of the compound. We believe this alteration allows the drug to stay in the cancer cell and act on its target.

Preclinical studies, however, often do not reflect subsequent human clinical trial success. PT-523 may prove to be poorly tolerated or ineffective in human clinical trials.

### ***Clinical Development Plan***

In March 2003, we submitted an Investigational New Drug application, or “IND,” with the United States Food and Drug Administration to seek approval to commence Phase I clinical trials of PT-523 for the treatment of cancer in humans. On May 30, 2003, we received notice from the FDA granting the IND, enabling us to initiate clinical trials in the U.S. In 2003, we received institutional review board approval to begin Phase I clinical studies at the Dana Farber Cancer Institute, Massachusetts General Hospital, and Beth-Israel Deaconess Hospital. Joseph Paul Eder, M.D., Assistant Professor of Medicine at Harvard Medical School and the Clinical Director of the Experimental Therapeutics Program, is the primary investigator for the Phase I clinical study, which commenced in March 2004.

The primary objectives of the study are to: (1) evaluate the safety of a short intravenous infusion of PT-523 when administered on days 1, 8, and 15 of a 28-day cycle to patients with solid tumors who have failed curative or survival prolonging therapy or for whom no such therapies exist; and (2) establish the maximum tolerated dose and identify the dose limiting toxicities of PT-523. The secondary objectives of this study are to determine the pharmacokinetics and to evaluate preliminary efficacy of PT-523 in patients receiving a short intravenous infusion of PT-523. A total of 20-40 patients are expected to be enrolled in this trial.

In February 2005 we began an open-label multicenter, multinational Phase I and II study of PT-523 in the treatment of relapsed or refractory non-small cell lung cancer or “NSCLC”. The primary objectives of the Phase I portion of this study are to: (1) evaluate the safety of PT-523 when administered on Days 1 and 8 of a 21-day cycle to NSCLC subjects who have failed curative or survival prolonging therapy or for whom no such therapies exist; and (2) establish the maximum tolerated dose and identify the dose limiting toxicities of PT-523. The primary objectives of the Phase II portion of this study are to evaluate the activity of PT-523 as therapy in subjects with NSCLC who have progressed on or following first-line therapy’s, as measured by overall survival. The secondary objectives of the Phase II portion of this study are: Evaluate the safety and tolerability of PT-523 in subjects with previously treated NSCLC; Assess the impact of PT-523 therapy in subjects with previously treated NSCLC, as measured by overall response rate, time to progression, and progression-free survival. The Phase I and II clinical trials will be conducted at five centers in United States and up to ten centers in Europe. A total of 120 patients are expected to enroll in the clinical trial. We expect that it will take at least an additional 4-5 years to complete development and obtain FDA approval of PT-523, if ever.

### ***Additional Potential Indications for PT-523***

While PT-523 continues in clinical development for oncology, we also intend to evaluate its potential in non-oncology indications, such as rheumatoid arthritis, psoriasis, inflammatory bowel disease, and multiple sclerosis. After initial preclinical studies are evaluated in each of the indications, our scientific advisory board, consultants, and management team will evaluate its potential in these indications. We then intend to pursue further clinical testing of PT-523 in the non-oncology indications that we believe show the most potential.

## **Competition**

We believe the efficacy and safety profile of PT-523 will make it an attractive alternative to existing antifolate therapies for oncology and inflammatory diseases. We intend to achieve market share at the expense of existing and established products, as well as future products in the relevant target markets. Some of our competitors include, but are not limited to, Eli Lilly (pemetrexed), Allos Therapeutics (pralatrexate), BioNumerik (MDAM), Eximias Pharmaceutical (nolatrexed), and BTG (plevitrexed).

*Currently Available Antifolates.* Cytotoxic agents such as antifolates have been in use for many years. Originally used as a chemotherapy drug to treat certain kinds of cancer, methotrexate was also found to be beneficial in those with inflammatory arthritis and psoriasis. In cancer, methotrexate has been used in breast, head and neck, lung, acute lymphocytic leukemia, gestational trophoblastic disease, lymphoma, and bone tumors. It is also used to treat rheumatoid arthritis and psoriasis. Trimetrexate is a methotrexate analog originally developed by Pfizer, which was approved in 1993 for the treatment of moderate-to-severe pneumocystis carinii pneumonia for immunocompromised patients.

Alimta (pemetrexed) by Eli Lilly & Company was granted accelerated approval in August 2004 as a single agent to treat locally advanced or metastatic non-small cell lung cancer that is refractory to chemotherapy. Alimta was originally approved in February 2004 for use in combination with cisplatin to treat patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery. According to SunTrust Robinson Humphrey, global sales of Alimta are estimated to be \$129 million in 2004. Possible advantages of PT-523 versus other compounds include increased targeting to tumor cells, better tolerability and superior resistance profile.

*Other Antifolates in Development.* In addition to the currently available antifolates discussed above, several of our competitors are also developing such products:

- Allos, under license from Memorial Sloan-Kettering Cancer Center, is developing a compound known as PDX (10-propargyl-10-deazaaminopterin). A Phase II trial in non-small-cell lung cancer has been completed and studies are ongoing in mesothelioma and lymphoma.
- Eximias Pharmaceuticals, under license from Agouron, is developing an IV formulation of nolatrexed (nolatrexed dihydrochloride, Thymitaq®), a thymidine synthase inhibitor, for the potential treatment of cancer (the lead indication being unresectable hepatocellular carcinoma (HCC)).

PT-523 will also compete with other cytotoxic, or anticancer, therapies such as antimetabolites, alkylating agents, cytotoxic antibiotics, vinca alkaloids, platinum compounds, and taxanes. Since there is a considerable amount of overlap in their mechanisms of action, the choice of a particular agent or group of agents is generally not a consequence of a prior prediction of antitumor activity by the drug, but instead the result of empirical clinical trials.

## **IPdR: Product Description**

### **Overview**

Our second product candidate, IPdR, is a radiation therapy sensitizer that we are developing for use in the treatment of certain types of brain cancers. When used in conjunction with radiation therapy, a sensitizer potentially makes the tumor area more likely to be damaged by the radiation. We license our rights to develop and commercialize IPdR from Yale University and the State University of New York pursuant to the terms of a February 2004 license agreement.



## ***Product Description***

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 to grow. Although radiation damages both cancer cells and normal cells, the latter are able to repair themselves and function properly. 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).

Two types of investigational drugs are being studied for their effect on cells undergoing radiation. Radiosensitizers, such as IPdR, potentially make the tumor cells more likely to be damaged, and radioprotectors, which protect normal tissues from the effects of radiation. Hyperthermia, the use of heat, is also being studied for its effectiveness in sensitizing tissue to radiation.

IPdR is a novel oral prodrug of the compound 5-iodo-2'-deoxyuridine, more commonly known as IUdR, being developed as a radiation therapy sensitizer for the treatment of certain types of brain cancers. Prodrugs are compounds that are converted within the body into their active form that has medical effects. IPdR is converted to IUdR by the enzyme aldehyde oxidase in the liver. Preclinical studies with IPdR in several animal models demonstrated that IPdR and radiation is superior in terms of safety and efficacy versus IUdR and radiation or radiation alone. While the toxicity of intravenously administered IUdR limits the duration and dose rate of treatment, it is believed that the decreased toxicity of orally administered IPdR makes it potentially useful in the radiation treatment. Preclinical studies, however, often do not reflect subsequent human clinical trial success. IPdR may not prove to be well tolerated or effective in human clinical trials.

## ***Clinical and Regulatory Development Plan***

The clinical development strategy for IPdR is to improve the therapeutic index of IUdR radiosensitization in poorly responsive (clinically radioresistant) human tumors. To achieve this, we propose to use a less systemically toxic halogenated analogue that can be metabolized in the body to the active drug by the liver. Based on preclinical studies, the use of orally administered IPdR as a prodrug for IUdR-mediated tumor radiosensitization may achieve this goal.

The first potential indication for the use of IPdR will be for malignant brain tumors. Glioblastoma multiforme and anaplastic astrocytoma are the two most common forms of malignant brain tumor. They are highly aggressive, locally invasive, and poorly responsive to most treatments. Overall, the incidence of anaplastic astrocytoma and glioblastoma multiforme in the United States is 12,000 new cases each year, which account for more than 50 percent of all primary brain tumors diagnosed each year in the United States each year. Malignant gliomas are typically diagnosed later in life, with a median age at diagnosis of 62 years. The incidence of malignant glioma has been increasing in the elderly population in recent years.

The reason for initially targeting malignant gliomas is that radiation therapy is the standard treatment for this cancer. Additionally, because these tumors are highly aggressive, standard endpoints such as increase in survival can be replaced by increased tumor response or decreased toxicity in these patients.

We plan to request a pre-IND meeting with the FDA in 2005 to review the IPdR preclinical program and to obtain comment on the proposed clinical protocol. Once our IND has been accepted, we will begin our Phase I studies, which we estimate will take 12 months to complete. After the completion of this study, we expect to begin a Phase II study for malignant gliomas. After the completion of that study and meeting with the FDA, we anticipate initiating several additional Phase II and III studies. We envision these studies being done for primary brain tumor and for the treatment of brain metastases. Upon completion of these studies, and having a pre-NDA meeting with the FDA, we hope to use data from these studies to file a NDA. We estimate NDA approval and market launch in 2009. Also, development timelines may potentially be shorter through FDA “Fast Track” review due to the likelihood of orphan drug designation, high unmet medical need, and high rate of disease progression.

### ***Competition***

Currently, there are no approved radiation sensitizers on the market. Two late stage radiation sensitizers in clinical development are Efaproxyn (RSR13) and Xcytrin (motexafin gadolinium). RSR13, being developed by Allos, is a synthetic small molecule that enhances the diffusion of oxygen to hypoxic tumor tissues from hemoglobin. A Phase III study, known as ENRICH (Enhancing Whole Brain Radiation Therapy in Patients with Breast Cancer and Hypoxic Brain Metastases), is designed to compare the effect of whole brain radiation therapy with supplemental oxygen with or without Efaproxyn in women with brain metastases originating from breast cancer.

Xcytrin, being developed by Pharmacyclics, is an anti-cancer agent with a novel mechanism of action that is designed to selectively concentrate in tumor and induce cancer cell death. Xcytrin has been granted Fast-Track status by the FDA for the treatment of brain metastases (cancer that has spread to the brain from another part of the body) in non-small cell lung cancer (NSCLC) patients. Xcytrin is currently being evaluated in a randomized Phase III clinical trial (the SMART trial) designed to compare the effects of whole brain radiation therapy alone to whole brain radiation therapy plus Xcytrin for the treatment of brain metastases in patients suffering from NSCLC.

## **Ondansetron Lingual Spray**

### ***Overview***

Our third product candidate, ondansetron lingual spray, or “OLS,” is a novel delivery system that utilizes highly-absorptive surfaces of the oral mucosa to deliver ondansetron, widely used to prevent chemotherapy-induced nausea and vomiting, directly into the bloodstream with the potential of achieving therapeutic levels in a shorter period of time than conventional oral dosage forms. We licensed our rights to develop and commercialize OLS in the U.S. and Canada from NovaDel Pharma, Inc. pursuant to the terms of an October 2004 license agreement.

### ***Product Description***

OLS is a novel delivery system that utilizes the vast and highly-absorptive surfaces of the oral mucosa to deliver ondansetron directly into the bloodstream and achieving therapeutic levels in a shorter period of time than conventional oral dosage forms. Ondansetron is a selective blocking agent of the serotonin 5-HT<sub>3</sub> receptor type and is widely accepted as the standard of care to prevent chemotherapy-induced nausea and vomiting.

OLS may provide increased convenience and efficacy for cancer patients experiencing nausea and vomiting. Drug delivery across the oral mucosa avoids delays associated with tablet dissolution, gastrointestinal transit and absorption of conventional tablet and orally dissolving tablet formulations. Therefore, the proprietary lingual spray formulation of ondansetron is expected to more rapidly alleviate nausea and vomiting as compared to current oral formulations of the drug. In addition, small doses of ondansetron are expected to be required since lingual spray delivery avoids the “first pass effect” -metabolism and degradation of the active ingredient by the liver - of orally administered ondansetron.

Ondansetron is currently approved in the U.S. by the FDA and is currently being marketed by GlaxoSmithKline under the name Zofran® for the following indications:

1. Prevention of nausea and vomiting associated with highly emetogenic (i.e., vomit-inducing) cancer chemotherapy.
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
3. Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
4. Prevention of postoperative nausea and/or vomiting. As with other antiemetics (i.e., agents that prevent or reduce vomiting), routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, ZOFRAN® Tablets, ZOFRAN® ODT Orally Disintegrating Tablets, and ZOFRAN® Oral Solution are recommended even where the incidence of postoperative nausea and/or vomiting is low.

### ***Clinical and Regulatory Development Plan***

The clinical development strategy for OLS is focused on identifying a formulation that provides a dose of ondansetron that is equivalent to the approved 8 mg formulations in terms of overall, systemic exposure to the active ingredient. In addition, the development strategy will provide support for potential advantages of the OLS formulation such as time to therapeutic effect or convenience in dispensing and administration.

As an initial step, several candidate formulations of various strengths have been tested as single doses in healthy volunteers in order to identify a formulation that achieves therapeutic levels similar to Zofran® 8 mg tablet. On the basis of this study, the optimal OLS formulation will be selected and clinical supplies prepared in a container configuration to provide a consistent 8 mg metered dose. An IND application for this product will be filed with the FDA in order to conduct a pilot pharmacokinetic study in healthy adult volunteers to compare the OLS formulation with various marketed reference formulations of ondansetron.

The pivotal bioavailability/bioequivalency study and the container configuration is expected to be completed by the fourth quarter of 2005. In parallel, we also intend to initiate scale-up and validation of the manufacturing process. Pharmacokinetic and therapeutic properties of the OLS product manufactured at pilot scale will be confirmed.

Approval of OLS will be sought through the 505(b)(2) NDA registration process. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act permits the FDA, in its review of an NDA, to rely on a previous FDA finding of safety and efficacy for a related drug. The 505(b)(2) approval pathway is distinguished from the ANDA or generics route by the requirement that drug products approved under this section must have significant difference relative to the reference approved product. The additional information in the 505(b)(2) applications can be provided by literature or reference to past FDA findings of safety and effectiveness for approved drugs, or it can be based upon studies conducted by or for the applicant to which it has obtained a right of reference. The majority of 505(b)(2) applications are filed for new formulations of drugs which are widely used, like ondansetron, so there is an understanding on the part of the FDA, as well as the medical community on their pharmacokinetics, safety and efficacy.

OLS recently completed a study where the pharmacokinetic profile was compared to the 8 mg Zofran® tablet. The study demonstrated that the ability to deliver OLS via the lingual spray technology produced a similar pharmacokinetic profile to the currently marketed oral tablet. Also concluded was that the time to achievement of measurable drug concentration was about 20 minutes shorter for 8 mg OLS versus 8 mg Zofran® tablet. Also, at 20 minutes post-dose, the OLS formulation significantly increased the total amount of drug delivered and the mean ondansetron plasma concentration relative to the conventional oral tablet. Based on successful results of this pilot pharmacokinetic trial in healthy volunteers, we intend to file an Investigational New Drug (IND) Application to commence an abbreviated clinical development program designed to support a 505(b)(2) submission, a form of New Drug Application (NDA) that relies on data in previously approved NDAs and published literature. If the results are successful, we expect the oral spray version to be available in 2007.

### ***Competition***

Since the introduction of Zofran® (ondansetron), the 5-HT<sub>3</sub> class of treatment has grown significantly, with the introduction of three other US marketed antiemetics (i.e. products that prevent vomiting and nausea) - Kytril (granisetron), Anzemet (dolasetron) and most recently, Aloxi (palonosetron). The two formulations most commonly prescribed for chemo-induced nausea and vomiting are the tablet and IV forms. Emend (aprepitant), an NK1 inhibitor, is the only FDA-approved agent for the prevention of delayed nausea and vomiting associated with highly emetogenic chemotherapy.

In addition to the currently branded antiemetics, there will be generic versions of ondansetron after the patent for Zofran® expires in December 2006. Dr. Reddy's Lab, Par Pharmaceuticals, and Mayne Pharmaceuticals have all submitted abbreviated new drug applications for the three formulations of ondansetron. After the launch of the generic versions, each of them will have 180 day exclusivity for the sale of their respectively approved formulation.

### **Government Regulation**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the "FDCA," and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

***Drug Approval Process.*** None of our drugs may be marketed in the U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- preclinical laboratory tests, animal studies, and formulation studies,
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin,
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication,
- submission to the FDA of an NDA,
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or "cGMPs," and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that Phase I, Phase II, or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, the Company or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as Special Protocol Assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The agencies review the application and may deem it to be inadequate to support the registration and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

Section 505(b)(2) of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or a prior FDA approval of an NDA for a related drug. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require postmarketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

**Post-Approval Requirements.** Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

**Orphan Drug.** The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication.

***Non-United States Regulation.*** Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all EU members states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

## **License Agreements and Intellectual Property**

### ***General***

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve its trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for its product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and abroad. However, even patent protection may not always afford complete protection against competitors who seek to circumvent patents. *See* “Risk Factors - Risks Relating to Our Business - If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish,” following Item 1 of this Annual Report.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely and intend to rely in the future on trade secret protection and confidentiality agreements to protect our interests.

### ***License Agreements***

**PT-523.** Our rights to PT-523 are governed by the terms of a December 2002 license agreement with Dana-Farber Cancer Institute and Ash Stevens, Inc. The agreement provides us with an exclusive worldwide royalty bearing license, including the right to grant sublicenses, to the intellectual property rights and know-how relating to PT-523 and all of its uses. Patents related to this technology and covered by the license include: (i) a composition of matter patent, (ii) a utility application, and (iii) provisional use patents for multiple indications. The technology licensed to us includes one United States patent issued in 1988 and one pending patent application filed in April 2003.

Upon execution of the license agreement, we paid a license fee of \$100,000 to our licensors and also reimbursed them for patent-related expenses in an amount of approximately \$11,000. In addition, the license agreement requires us to make future payments totaling up to \$6 million upon the achievement of certain milestones, including a \$5 million payment upon approval by the FDA of a New Drug Application for PT-523. To date, we have made one of these milestone payments in the amount of \$100,000 following commencement of the Phase I clinical trial. Additionally, we are obligated to pay royalties in the amount of 3.5 percent of “net sales” (as defined in the license agreement) of PT-523. We are also required to pay to the licensors 20 percent of fees or non-royalty consideration (e.g., milestone payments, license fees) received by us in connection with any sublicense of PT-523 granted prior to the start of a Phase II trial, and 15 percent of such fees after initiation of a Phase II clinical trial.

The license agreement includes certain other covenants, which require us to, among other things, maintain and prosecute patents related to PT-523; use our commercially reasonable efforts to bring the licensed product to market as soon as reasonably practicable; and prepare and provide to the licensors certain reports concerning our development and commercialization efforts. In the event we fail to carry out our responsibilities under the license agreement, the licensors may terminate the license. The license agreement may also be terminated in the event we fail to make a scheduled milestone or royalty payment, we otherwise materially breach the license agreement, or if we become involved in a bankruptcy, insolvency or similar proceeding, provided that we are entitled to notice of such intention to terminate and an opportunity to cure.

The license agreement automatically expires, on a country-by-country basis, on the date on which the last of the patent claims covered by the agreement expires, lapses or is declared invalid by a court of competent jurisdiction in such country. The first of the patents covered by the license agreement is set to expire in 2007, although the pending applications, if granted, will not expire until 2023.

**IPdR.** In February 2004, we entered into an exclusive worldwide, royalty-bearing license agreement with Yale University and The Research Foundation of State University of New York, including the right to grant sublicenses, for the rights to the intellectual property relating to IPdR. The licensed intellectual property includes patent rights relating to IPdR that do not expire until 2015, at the earliest. In addition to a \$100,000 license fee paid upon execution of the agreement, we issued to our licensors 10-year options to purchase an aggregate of approximately 141,000 shares of our common stock at a price of \$1.02 per share. We are also required to make an annual license payment of \$25,000 on the anniversary of the agreement. In addition, we are required to make milestone payments in the aggregate amount of \$500,000 upon the completion of a Phase IIb clinical trial and upon NDA approval by the FDA. As further consideration for the license, we are required to pay royalties to Yale and SUNY equal to 3 percent of net sales (as defined in the license agreement) from IPdR.

The license agreement also includes certain other covenants which obligate us to, among other things, initiate a Phase I trial for IPdR by February 2006 and a Phase II trial within 18 months of successful completion of the Phase I trial; file an NDA for FDA approval by February 2011; maintain and prosecute the patents relating to IPdR; and use our reasonable commercial efforts to implement a mutually-agreed upon plan for developing and commercializing IPdR. In the event we commit a material breach of our obligations under the license agreement, Yale and SUNY have the right to terminate the license agreement following notice to us and an opportunity to cure such breach (if capable of being cured).



The license agreement automatically expires, on a country-by-country basis, on the date on which the last of the patent claims covered by the agreement expires, lapses or is declared invalid by a court of competent jurisdiction in such country. The first of the two patents covered by the license agreement is set to expire in 2007 and the second is set to expire in 2015.

**Ondansetron Lingual Spray.** Pursuant to the terms of an October 2004 license agreement with NovaDel Pharma, Inc., we hold a royalty-bearing, exclusive right and license to develop and commercialize within the United States and Canada NovaDel's lingual spray version of ondansetron. The technology licensed to us under the license agreement currently covers one United States issued patent. In connection with the development of the licensed product, NovaDel has agreed to perform or cause to be performed certain development activities on behalf and at the expense of the Company.

In consideration for the license, the license agreement provides that (i) we will make double-digit royalty payments to NovaDel based on a percentage of "net sales" (as defined in the agreement); (ii) we are obligated to make various milestone payments in an aggregate amount of up to \$10 million; and (iii) we issued to NovaDel 73,121 shares of our common stock (determined by dividing \$500,000 by the average selling price of our common stock during the 10 business days preceding the date of the license agreement) and we purchased 400,000 shares of NovaDel's common stock at a price of \$2.50 per share. Neither party may sell such shares for a 2-year period following the effective date of the license agreement.

The license agreement expires on the later of (i) the expiration date of the last to expire patent covered by the license (currently March 2022) or (ii) 20 years from the effective date of the license agreement. The license agreement also provides that NovaDel may terminate the agreement upon notice prior to the expiration of its term in the event the Company becomes insolvent or defaults in its payment obligations, and either party may terminate the agreement after giving notice and an opportunity to cure in the event the other party commits a material breach.

## **Legal Proceedings**

We are not subject to any pending legal proceeding, nor are we aware of any threatened claims against us.

## **Properties**

We lease 5,942 square feet of office space in South San Francisco, California. This lease currently requires us to make monthly payments of approximately \$10,100. The lease expires December 31, 2005, although we have the option to extend the lease for an additional year at the same base rent. We do not own any real property. We believe that our existing facilities are adequate to meet our needs for the foreseeable future.

## **Employees**

We currently employ 11 persons, all of whom are based at our South San Francisco office. We believe the relationships with our employees is satisfactory.

## MANAGEMENT

Our executive officers, key employees and directors are described below. There are no family relationships among our executive officers or directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Mark J. Ahn, Ph.D.	42	President, Chief Executive Officer and Director
Gregory I. Berk, M.D.	46	Vice President - Chief Medical Officer
Russell L. Skibsted	45	Vice President - Chief Financial Officer and Secretary
Fred Vitale	48	Vice President - Business Development
John P. Iparraguirre	29	Controller
Arie Beldegrun, M.D.	55	Director
Isaac Kier	52	Director
Leon Rosenberg, M.D.	71	Director
Michael Weiser, M.D., Ph.D.	42	Director

**Mark J. Ahn, Ph.D.** has been our President and Chief Executive Officer and a member of our board of directors since November 2003. Prior to joining our company, from December 2001 to November 2003, he served as Vice President, Hematology and corporate officer at Genentech, Inc. where he was responsible for commercial and clinical development of the Hematology franchise, which surpassed \$1 billion in annual revenues. From February 1991 to February 1997 and from February 1997 to December 2001, Dr. Ahn was employed by Amgen and Bristol-Myers Squibb Company, respectively, holding a series of positions of increasing responsibility in strategy, general management, sales & marketing, business development, and finance. He has also served as an officer in the U.S. Army. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute, founder of the Center for Non-Profit Leadership, Board of Director for Transmolecular, Inc., a privately held biotechnology company focused on neuroncology, and a member of the Board of Trustees for the MEDUNSA (Medical University of South Africa) Trust. Dr. Ahn received a BA in History and an MBA in Finance from Chaminade University. He was a graduate fellow in Economics at Essex University, and has a Ph.D. in Business Administration from the University of South Australia.

**Gregory I. Berk, M.D.** has served as Vice President - Chief Medical Officer since October 2004. From January 2003 until he joined our company, Dr. Berk was Medical Director for Network of Medical Communications and Research where he provided clinical development strategy consulting for leading global oncology companies. From July 1990 to December 2002, Dr. Berk practiced oncology in New York as a partner in Richard T. Silver, M.D. and Gregory I. Berk, M.D., P.C. and was Attending Physician, Department of Medicine at New York Presbyterian Hospital (Cornell Campus) from June 1989 to December 2002. From July 1995 to December 2002, Dr. Berk was Assistant Professor of Medicine, Weill Medical College, Cornell University, New York, where he also served an investigator in numerous clinical trials for oncology product candidates, including the Gleevec pivotal trials, Avastin colorectal and breast trials, and several CALGB studies. Dr. Berk received an M.D. in 1984 from Case Western Reserve University School of Medicine in Cleveland, Ohio.

**Russell L. Skibsted** has been our Vice President - Chief Financial Officer and Secretary since November 2004. From May 2000 until July 2004, Mr. Skibsted was Chief Financial Officer and Portfolio Management Partner of Asset Management Company, a 40yr old Silicon Valley-based venture capital firm that was a founding investor in firms such as Amgen & IDEC Pharmaceuticals. From March 1997 to May 2000, Mr. Skibsted served as Vice President in the Structured Finance Group of GE Capital Services. Prior to that, Mr. Skibsted was Director of Corporate Development at Pinkerton's, Inc. from January 1996 to March 1997. Prior, Mr. Skibsted co-founded two firms in the real estate industry. From October 2001 to August 2002, Mr. Skibsted served on the board of directors of TCSI Corporation, a software company based in the Bay Area. Mr. Skibsted holds a MBA from the Stanford University Graduate School of Business and a bachelor's degree in economics from Claremont McKenna College.

**Fred Vitale** has served as Vice President, Business Development of Hana since January 2004. From April 2001 to January 2004, Mr. Vitale was employed by Genentech, where he served as head of commercial Rituxan (rituximab) and pre-launch medical education for Avastin (bevacizumab). From December 1998 to April 2001, Mr. Vitale was Director, Global Oncology Marketing at Bristol-Myers Squibb where he was responsible for pipeline development, licensing, and life cycle management for cancer products including Taxol (paclitaxel); as well as Director of Operations and Planning for Japan and China. Prior to that, Mr. Vitale held several roles of increasing responsibility in sales, marketing and general management at Amgen from January 1990 to December 1998. Mr. Vitale received a Bachelor of Science in Biology from The Citadel in Charleston, South Carolina and a Physician Assistant degree from the Medical University of South Carolina.

**John P. Iparraguirre** has served as Controller of our company since May 2004. He also served as interim Chief Financial Officer and Secretary from August 2004 to November 2004. Prior to joining Hana, Mr. Iparraguirre was the Accounting Manager at Discovery Toys, Inc. from April 2002 until May 2004 where he held several roles of responsibility in Finance Management. Mr. Iparraguirre was primarily responsible for maintaining the integrity of the company's financial reporting as well as coordinating all aspects of its SEC regulatory filings. Prior to Discovery Toys, Mr. Iparraguirre was a Senior Audit Associate at BDO Seidman, LLP, an international accounting firm, from September 1998 until April 2002, focusing on publicly traded companies and their related SEC compliance. In addition, he was appointed the West Coast administrator for BDO's Computer Assisted Auditing Tools. Mr. Iparraguirre received a Bachelor of Science degree in Business Economics with an Emphasis in Accounting from the University of California, Santa Barbara.

**Arie Beldegrun, M.D., FACS** has served on Hana's Board of Directors since April 2004. He has served as Professor of Urology since 1994, Chief of the Division of Urologic Oncology since 1996 at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). He has also held the Roy and Carol Doumani Chair in Urologic Oncology at UCLA since 2000. Dr. Beldegrun completed his medical degree at the Hebrew University Hadassah Medical School in Jerusalem, his post at the Weizmann Institute of Science and his residency in Urology at Harvard Medical School. Prior to UCLA, Dr. Beldegrun served as a research fellow in surgical oncology at the National Cancer Institute/NIH under Steven A. Rosenberg, MD, Ph.D. from 1985 to 1988. He is certified by the American Board of Urology and is a Fellow of the American College of Surgeons. Dr. Beldegrun is on the scientific boards of several biotechnology and pharmaceutical companies and serves as a reviewer for many medical journals and granting organizations. In addition to holding several patents, Dr. Beldegrun is the author of several books on prostate and kidney cancers, and has written over 350 scientific publications with an emphasis on urologic oncology, particularly kidney, prostate and bladder cancers. He is the founder of Agensys, Inc., a company focused on the development of fully human monoclonal antibodies to treat solid tumor cancers based on Agensys' propriety targets. Dr. Beldegrun served as founding Chairman of Agensys from 1997-2002 and currently serves on the Board of Directors and as a consultant. Dr. Beldegrun is also Vice Chairman of the Board of Directors and Chairman of the Scientific Advisory Board of Cougar Biotechnology, Inc., established to in-license and develop early clinical stage drugs, with a specific focus on the field of oncology.

**Isaac Kier** has served on Board of Directors of Hana since February 2004. Since February 2000, Mr. Kier has been a general partner of Coqui Capital Partners, a venture capital firm licensed by the Small Business Administration as a small business investment company having investments in the telecommunications, media and biotechnology industries. Since February 2004, he has served as treasurer and director of Tremisis Energy Acquisition Corporation (TEGYU.OB), a special purpose acquisition company. He served as President, Chief Executive Officer and Chairman of the Board of Lida, Inc (Nasdaq: LIDA) from 1981 until 1995. He was a lead investor in eDiets.com (Nasdaq:DIET) in 1999. Mr. Kier has served on the board of directors of private companies such as Montebello Brand Liquors, Inc. since 2001, and Caribbean Storage, Inc. since 2000. Since April 1997, he has been a principal of First Americas Partners, LLC, an investment partnership focusing on real estate investments in North and South America. From 1987 to 1997, he also served as the Managing Partner of Dana Communications Limited, a non-wire-line cellular licensee. Mr. Kier received a BA in Economics from Cornell University and a JD from George Washington University Law School.

**Leon E. Rosenberg, M.D.**, a director of Hana since February 2004, has been a Professor in the Princeton University Department of Molecular Biology and the Woodrow Wilson School of Public and International Public Affairs since September 1997. Since July 1999, he has also been Professor Adjunct of Genetics at Yale University School of Medicine. From January 1997 to March 1998, Dr. Rosenberg served as Senior Vice President, Scientific Affairs of Bristol-Myers Squibb Company, and from September 1991 to January 1997, Dr. Rosenberg served as President of the Bristol-Myers Squibb Pharmaceutical Research Institute, where he was responsible for the company's worldwide pharmaceutical research and development. Prior to Bristol-Myers Squibb, Dr. Rosenberg was Dean of the Yale University School of Medicine from July 1984 to September 1991. Dr. Rosenberg also serves on the Boards of Directors of Lovelace Respiratory Research Institute (since 1997), Karo Bio AB (since 2000), and Medicines for Malaria Venture (since 2000).

**Michael Weiser, M.D., Ph.D.**, a director of Hana since its inception in December 2002, is the Director of Research of Paramount BioCapital Asset Management, Inc., New York. Dr. Weiser also currently serves on the boards of directors of Manhattan Pharmaceuticals, Inc. (OTCBB: MHTT), a company engaged in developing pharmaceutical technologies, since February 2003, VioQuest Pharmaceuticals, Inc., formerly Chiral Quest, Inc. (OTCBB: VQPH), since February 2003, Innovative Drug Delivery Systems, Inc. and several other privately-held biotechnology companies. Dr. Weiser completed his Ph.D. in Molecular Neurobiology at Cornell University Medical College and received his M.D. from New York University School of Medicine, where he also completed a Postdoctoral Fellowship in the Department of Physiology and Neuroscience.

## **Code of Ethics**

We have a Code of Ethics that applies to our senior financial officers, including our President and Chief Executive Officer. A copy of the Code of Ethics may be obtained without charge upon written request directed to Hana Biosciences, Inc., Attn: Secretary, 400 Oyster Point Boulevard, Suite 215, South San Francisco, California 94080.

## **Audit Committee Financial Expert**

We have an Audit Committee composed of Mr. Kier and Drs. Belldegrun and Rosenberg. Our board of directors has determined that Mr. Kier qualifies as an "audit committee financial expert," as that term is defined by SEC regulations. As indicated above, Mr. Kier has experience as the treasurer (principal financial officer) of a publicly held company. Although our common stock is not listed on any of the New York Stock Exchange, American Stock Exchange or the Nasdaq Stock Market, applicable SEC rules require us to determine whether Mr. Kier is also an "independent director," as that term is defined by the listing standards of one of the foregoing stock markets. Mr. Kier is also an "independent director," as that term is defined by Rule 4200(a)(15) of the Nasdaq listing requirements.

## Compensation of Executive Officers

Prior to the appointment of Mark J. Ahn, Ph.D. as Hana Biosciences' president and chief executive officer in November 2003, since its inception in December 2002, the company had never paid any cash or other compensation to any executive officer or director. Further, prior to Dr. Ahn's appointment, none of Hana Biosciences officers or directors ever received any stock options, stock appreciation rights, stock awards or other stock-based compensation.

The following table sets forth, for each of Hana Biosciences' completed fiscal years since its inception in December 2002, the compensation earned for services rendered in all capacities by Dr. Ahn, our chief executive officer, and our other executive officers serving at the end of 2004 and whose salary and bonus compensation for that year exceeded \$100,000. No other executive officer serving as of December 31, 2004 received compensation in excess of \$100,000 in 2004.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation Awards	All Other Compensation
		Salary(\$)	Bonus(\$)	Other Annual Compensation (\$)	Securities Underlying Options (#)	(\$)(1)
Mark J. Ahn (2) President & Chief Executive Officer	2004	250,000	187,500	0	458,781	12,500
	2003	41,667	80,000	0	493,524	0
	2002	--	--	--	--	--
Fred L. Vitale(3) Vice President, Business Development	2004	163,731	128,904	0	141,007	8,750
	2003	--	--	--	--	--
	2002	--	--	--	--	--

(1) Represents annual contributions to the Company's defined benefit plan.

(2) Dr. Ahn's compensation for 2003 represents amounts received from his hiring on November 1, 2003, which included an \$80,000 signing bonus and the prorated amount of his \$250,000 annual base salary. The number of securities underlying options granted to Dr. Ahn reflect an original option grant relating to 350,000, which as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination, converted into the right to purchase 493,524 shares of common stock.

(3) Mr. Vitale's compensation for 2004 represents amounts received from his hiring on January 25, 2004, which included a \$40,000 signing bonus and the prorated amount of his \$175,000 annual base salary. The number of securities underlying options granted to Mr. Ahn reflect an original option grant relating to 100,000, which as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination, converted into the right to purchase 141,007 shares of common stock.

(4) Mr. Ahn is also eligible to receive an annual performance-based bonus to be determined in the discretion of the Board of Directors. As of the date of the filing of this report, the Board of Directors had not yet determined the amount of such performance-based bonus for fiscal 2004.

## Options and Stock Appreciation Rights

The following table contains information concerning the grant of stock options under our 2003 and 2004 Stock Option Plan and otherwise to the Named Officer during the 2004 fiscal year. No stock appreciation rights were granted during the 2004 fiscal year.

### Option Grants in Last Fiscal Year (Individual Grants)

Name	Number of Securities Underlying Options Granted (#)	Percent of Total Options/SARs Granted to Employees in Fiscal Year	Exercise or Base Price (\$/Share)	Expiration Date
Mark J. Ahn	184,555 <sup>(1)</sup>	13.2	0.167	2/15/2014
	79,658 <sup>(2)</sup>	5.7	0.167	2/26/2014
	194,568 <sup>(3)</sup>	14.0	0.167	7/20/2014
Fred L. Vitale	141,007 <sup>(4)</sup>	10.1	0.336	2/1/2014

- (1) Option vests in three equal installments on February 15, 2005, February 15, 2006 and February 15, 2007, respectively. The number of shares relating to the option was originally 130,884 at a price of \$0.235 per share, which, as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination converted into the right to purchase 184,555 shares at a price of \$0.167 per share.
- (2) Option vests in three equal installments on February 26, 2005, February 26, 2006 and February 26, 2007, respectively. The number of shares relating to the option was originally 56,492 at a price of \$0.235 per share, which, as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination converted into the right to purchase 79,658 shares at a price of \$0.167 per share.
- (3) Option vests in three equal installments on July 20, 2005, July 20, 2006 and July 20, 2007, respectively. The number of shares relating to the option was originally 137,984 at a price of \$0.235 per share, which, as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination converted into the right to purchase 194,568 shares at a price of \$0.167 per share.
- (4) Option vests in two equal installments on February 1, 2005 and February 1, 2006, respectively. The number of shares relating to the option was originally 100,000 at a price of \$0.474 per share, which, as a result of the July 2004 merger with EMLR, Inc. and September 2004 stock combination converted into the right to purchase 141,007 shares at a price of \$0.336 per share.

## Option Exercise and Holdings

The following table provides information with respect to Dr. Ahn and Mr. Vitale concerning the exercisability of options during the 2004 fiscal year and unexercisable options held as of the end of the 2004 fiscal year. No stock appreciation rights were exercised during the 2004 fiscal year, and no stock appreciation rights were outstanding at the end of that fiscal year.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

Name	Shares Acquired on Exercise	Value Realized	Securities Underlying Unexercised Options at FY-End (#)		Value of Unexercised In-the- Money Options at FY-End (Market price of shares at FY-End less exercise price) <sup>(1)</sup>	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Dr. Ahn	0	--	\$164,508	\$787,797	\$943,124	\$4,469,822
Mr. Vitale	0	--	\$0	\$141,007	\$0	\$784,563

(1) Based on the fair market value of our common stock on December 31, 2004 of \$5.90 per share, the closing sales price per share on that date on the OTC Bulletin Board, as adjusted.

**Long Term Incentive Plan Awards**

No long term incentive plan awards were made to any executive officer during the last fiscal year.

**Compensation of Directors**

Our non-employee directors receive a cash fee of \$2,500 for each meeting they attend. Non-employee directors may be granted, at the discretion of the Board, options to purchase shares of our common stock. Such options shall contain such terms and provisions as the Board determines at the time of grant. In February 2004, each of Isaac Kier, Leon Rosenberg and Arie Belldegrun received options to purchase 28,201 shares of our common stock at a price of \$1.68 per share, in consideration for their services as directors. All of these options vest in three equal installments on each anniversary of the grant date until fully vested. In addition, Mr. Kier was granted 10,000 shares of common stock in 2004 in consideration for his service as chair of the audit committee. These shares were issued in January 2005.

**Employment Contracts and Termination of Employment and Change of Control Agreements**

***Mark J. Ahn, Ph.D.***

Dr. Ahn's employment with us is governed by an employment agreement dated November 1, 2003. The agreement provides for a term of 3 years with an annual base salary of \$250,000. Dr. Ahn is also eligible to receive milestone bonus payments, as follows: (i) \$50,000 upon the dosing of the first patient in a Phase II clinical trial of PT-523; (ii) \$75,000 upon the dosing of the first patient in a Phase III clinical trial of PT-523; (iii) \$75,000 upon the in-licensing of a Phase II clinical compound introduced to us by Dr. Ahn; (iv) \$100,000 upon our licensing of a Phase III clinical compound introduced to us by Dr. Ahn; (v) \$50,000 following the successful completion of an initial public offering; and (vi) \$100,000 in the event that our market capitalization is at least \$100 million for a period of 90 consecutive days. Dr. Ahn is further eligible to receive an annual bonus in an amount up to 75 percent of his base salary, as determined by our board of directors. Pursuant to his employment agreement, Dr. Ahn also received an option to purchase 493,524 shares of our common stock at a price of \$0.167 per share.

In addition to Dr. Ahn's initial option grant that he received upon joining Hana, his employment agreement also provides that he is entitled to receive additional option grants in the future in order to maintain his beneficial ownership of Hana's common stock at specified levels. In particular, his agreement provides that until such time as we raise aggregate gross proceeds of \$10 million through the sale of equity securities, we are required to issue Dr. Ahn an additional number of options sufficient to maintain his ownership percentage of our common stock at no less than 8 percent. Thereafter, and until we have raised an aggregate of \$50 million through the sale of equity securities, Dr. Ahn is entitled to receive additional options to maintain his ownership at no less than 5 percent (assuming the exercise of all options held by Dr. Ahn, without regard to the vesting schedule). Once we have raised at least \$50 million, then Dr. Ahn is no longer entitled to such additional options. Dr. Ahn's employment agreement provides that such additional stock options will vest in 3 annual installments beginning on the first anniversary of the grant date and shall be exercisable at a price equal to the greater of 20 percent of the then-current market price of our common stock or \$0.167 per share. Our obligation to issue any such additional stock options, if any, is triggered on the last day of each fiscal quarter in which we issued additional shares of common stock that resulted in Dr. Ahn's ownership percentage decreasing below the 8 or 5 percent levels, unless we sell any shares of common stock as part of a financing transaction, in which case the additional options are to be issued as of the closing of such transaction. In accordance with the terms of his employment agreement, we made two additional stock option grants to Dr. Ahn in 2004, consisting of a grant of 79,658 shares in February 2004 and a grant of 194,568 shares in July 2004. As of December 31, 2004, we have raised an aggregate of approximately \$12.7 million through the sale of our equity securities.

In the event we terminate Dr. Ahn's employment for "cause" (as defined in the employment agreement), it is only obligated to pay his compensation through the date of termination and all unvested options then held by Dr. Ahn immediately terminate. In the event Dr. Ahn's employment is terminated upon the occurrence of a "change of control" or for a reason other than for "cause," we are obligated to continue paying to Dr. Ahn his base salary for a period of one year, as well as any accrued and unpaid bonus through the date of termination; provided, that our obligation to pay Dr. Ahn such amounts shall be reduced by amounts he otherwise earns during the 1-year period following termination. In the event his employment is terminated upon a change of control, all of Dr. Ahn's stock options that have not yet vested will accelerate and be deemed to have vested upon such termination; otherwise, the unvested portion of such options will terminate and he will have 90 days to exercise the vested portions of any options.

### ***Gregory I. Berk***

We have entered into a written employment agreement with Dr. Berk providing for a 3-year term and an initial annual base salary of \$150,000, as well as a \$25,000 signing bonus, a housing allowance and other benefits generally made available to the Registrant's other senior management. The employment agreement also provides that Dr. Berk is entitled to receive an option to purchase 150,000 shares of our common stock at a price of \$2.39 per share. The option shall vest in three equal annual installments. In the event Dr. Berk's employment is terminated by us upon a "change of control" (as defined in the employment agreement), Dr. Berk is entitled to receive his base salary for six months and all of his unvested stock options shall be deemed vested. If, prior to the end of the 3-year term, we terminate Dr. Berk's employment without "cause" or other than as a result of a "disability" (as those terms are defined in the agreement) or death, or if Dr. Berk terminates his employment for "good reason," then Dr. Berk is entitled to receive his base salary for a period of one year from the date of such termination.



### ***Russell L. Skibsted***

We have entered into a written employment agreement with Mr. Skibsted providing for a 3-year term and an initial annual base salary of \$175,000, as well as a \$40,000 bonus payable prior to January 15, 2005 and other benefits generally made available to our other senior management. The employment agreement also provides that Mr. Skibsted is entitled to receive an option to purchase 150,000 shares of our common stock at a price of \$2.39 per share. The option will vest in three equal annual installments, commencing November 2005. In the event Mr. Skibsted's employment is terminated by us upon a "change of control" (as defined in the employment agreement), he is entitled to receive his base salary for six months thereafter or the remainder of the term, whichever is longer, and all unvested portions of his stock option grant shall be deemed vested. If, prior to the end of the 3-year term, we terminate Mr. Skibsted's employment without "cause" or other than as a result of a "disability" (as those terms are defined in the agreement) or death or in connection with a change of control, then Mr. Skibsted is entitled to receive his base salary for a period of one year from the date of such termination, provided, however, that such amount shall be reduced by amounts Mr. Skibsted earns from other employment during such one-year period.

### ***Fred Vitale***

Mr. Vitale's employment with us is governed by an employment agreement dated January 25, 2004. The agreement provides for a term of 2 years, subject to 1-year renewals as mutually agreed upon by us and Mr. Vitale, with an annual base salary of \$175,000. Mr. Vitale also received a signing bonus of \$40,000 upon execution of the employment agreement and is eligible to receive periodic incentive bonuses upon the achievement of milestones to be determined by the chief executive officer in an amount not to exceed \$50,000. In connection with his employment agreement, Mr. Vitale was also granted stock options that now represent the right to purchase 141,007 shares of common stock, which vest in two equal installments on February 1, 2005 and February 1, 2006. The options are exercisable at a price equal to \$0.336 per share.

In the event Mr. Vitale's employment is terminated for "cause" (as defined in the employment agreement), we are only obligated to pay his compensation through the date of termination and all stock options held by Mr. Vitale that have not yet vested immediately terminate. In the event we terminate Mr. Vitale's employment upon a "change of control," then Mr. Vitale is entitled to continue receiving his base salary for a period of six months. All stock options that have not yet vested as of such date will be accelerated and deemed to have vested. If we terminate Mr. Vitale's employment agreement for a reason other than for cause or upon a change of control, he is entitled to receive his base salary for a period of one year, which amount may be reduced by any amounts earned by Mr. Vitale from other employment during such one-year period.

### **Certain Relationships and Related Transactions**

In connection with a private placement in February 2004, Hana Biosciences engaged Paramount BioCapital, Inc. as its placement agent and paid Paramount the sum of approximately \$327,000 as commissions for its services. Hana Biosciences also issued to Paramount a 5-year warrant to purchase 196,679 shares of common stock at an exercise price of \$2.375 per share, which now represents the right to purchase 277,330 shares at a price of \$1.68 per share. In connection with our April 2005 private placement, we paid Paramount a cash fee of \$52,500 and issued a 5-year warrant to purchase 58,593 common shares at a price of \$1.57 per shares as a result of an investment by two investors previously introduced to us by Paramount. Dr. Michael Weiser, a director of our company, is an employee of Paramount.

In the February 2004 private placement, Hana Biosciences sold 84,210 shares of its common stock for total proceeds of \$200,000 to Kier Family, LP, a limited partnership of which Isaac Kier, a director of our company, is general partner. In addition, Mr. Kier and his affiliates purchased 179,641 shares of our Series A Preferred Stock in the July 2004 private placement in exchange for aggregate proceeds of \$600,000. The terms on which Mr. Kier or his affiliates purchased these shares were identical to the terms in which the other investors in these offerings purchased shares. In our April 2005 private placement, Mr. Kier and his affiliates purchased 253,906 shares of our common stock at a price of \$1.28 per share and, in connection with such offering, received warrants to purchase an additional 76,171 shares at an exercise price of \$1.57 per share.

In October 2004, we entered into a license agreement with NovaDel, Inc. Dr. Lindsay A. Rosenwald owns approximately 26 percent of the outstanding common stock of NovaDel. Dr. Rosenwald also owns less than 5 percent of our common stock and trusts established for the benefit of members of Dr. Rosenwald's family beneficially collectively own approximately 25 percent of our common stock. Dr. Rosenwald also owns and controls Paramount BioCapital, Inc., which, as discussed above, employs Dr. Weiser.

In connection with our April 2005 private placement, Mark Ahn and his spouse each purchased 19,531 shares of our common stock at a price of \$1.28 per share and each received warrants to purchase an additional 5,859 common shares at an exercise price of \$1.57 per share. In the same offering, Fred Vitale purchased 23,437 common shares at \$1.28 and received a warrant to purchase an additional 7,031 shares.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of each class of our capital stock as of April 29, 2005 for (1) each person known by us to beneficially own more than 5% of each class of our voting securities, (2) each executive officer, (3) each of our directors and (4) all of our executive officers and directors as a group. The number of shares beneficially owned is determined under rules promulgated by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days of the date hereof, through the exercise or conversion of any stock option, convertible security, warrant or other right. Including those shares in the tables does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of capital stock listed as owned by that person or entity. Unless otherwise indicated, the address of each of the following persons is 400 Oyster Point Blvd, Suite 215, South San Francisco, CA 94080.

Name	Shares Beneficially Owned		Percent
Mark J. Ahn	476,866	(1)	2.6
Gregory I. Berk	0		--
Russell L. Skibsted	0		--
Fred Vitale	111,972	(2)	*
John P. Iparraguirre	24,101	(3)	*
Arie J. Belldegrun	9,400	(4)	*
Isaac Kier	1,004,538	(5)	5.6
Leon Rosenberg	9,400	(6)	*
Michael Weiser	550,667		3.1
All officers and directors as a group (9 persons)	2,186,944		11.8
R&R Biotech, LLC (7) 330 Madison Avenue New York, NY 10017	1,378,974		7.7
Lester E. Lipschutz 1650 Arch Street - 22 <sup>nd</sup> Floor Philadelphia, PA 19103	2,063,662	(8)	11.5
Atlas Equity I, Ltd. 181 W. Madison, Suite 3600 Chicago, IL 60602	1,768,410	(9)	9.9

\* less than 1 percent

- (1) Includes 417,086 shares issuable upon exercise currently vested options and 11,718 shares issuable upon the exercise of warrants.
- (2) Includes 70,504 shares issuable upon exercise of a vested option and 7,031 shares issuable upon the exercise of a warrant.
- (3) Includes 14,101 shares issuable upon exercise of a portion of an option that vests May 9, 2005.
- (4) Represents shares issuable upon exercise of a vested option.
- (5) Includes (a) 654,010 shares of common stock held by Coqui Capital Partners, L.P., of which 46,875 shares are issuable upon the exercise of a warrant; (b) 118,742 shares of common stock held by Kier Family Partners, L.P.; (c) 143,779 shares of common stock held by JIJ Investments, of which 23,437 shares are issuable upon the exercise of a warrant; (d) 5,859 shares issuable upon the exercise of a warrant;

and (e) 9,400 shares issuable upon exercise of options. Mr. Kier is general partner of both Coqui Capital Partners and Kier Family Partners and is a partner in JIJ Investments.

- (6) Represents shares issuable upon exercise of a vested option.
- (7) Thomas Pinou has voting and dispositive power over the shares held by R&R Biotech, LLC.
- (8) Based on Schedule 13G filed February 11, 2005.
- (9) Jacob Gotlieb has voting and dispositive power over the shares held by Atlas Equity I, Ltd.

**MARKET FOR COMMON EQUITY  
AND RELATED STOCKHOLDER MATTERS**

**Market for Common Stock**

From August 18, 2003 until September 30, 2004, our common stock traded on the on the OTC Bulletin Board under the symbol “EMLR.OB.” Since October 1, 2004, our common stock has traded on the OTC Bulletin Board under the symbol “HNAB.OB.” The following table lists the high and low sale price for our common stock as quoted, in U.S. dollars, by the OTC Bulletin Board, as applicable, during each quarter from August 18, 2003 to March 31, 2005. These quotations reflect inter-dealer prices, without retail mark-up, markdown, or commission and may not represent actual transactions. These quotations have been adjusted to reflect a 10-for-1 split of our common stock effected October 1, 2003 and the 1-for-12 combination effected in connection with our reincorporation on September 30, 2004. Trading on our common stock has been sporadic, exemplified by the low trading volume and many days upon which no trades occurred.

<b>Quarter Ended</b>	<b>Price Range</b>	
	<b>High</b>	<b>Low</b>
September 30, 2003	4.800	0.180
December 31, 2003	7.800	4.800
March 31, 2004	10.800	5.400
June 30, 2004	20.400	7.800
September 30, 2004	13.801	7.200
December 31, 2004	7.400	5.250
March 31, 2005	5.85	1.50

Since the completion of the EMLR - Hana Biosciences merger transaction in July 2004 through March 31, 2005, the market price of our common stock has ranged from a high of \$15.00 per share to a low of \$1.50 per share, as adjusted to reflect the 1-for-12 combination effected in connection with our September 30, 2004 reincorporation.

**Record Holders**

As of March 21, 2005, we had approximately 226 holders of record of our common stock.

**Dividends**

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in the foreseeable future.

**Equity Compensation Plan Information**

The following table summarizes our outstanding options that we have issued to officers, directors and employees of our company, as of December 31, 2004.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	--	\$--	--
Equity compensation plans not approved by stockholders -			
Outside any Plan (1)	875,489	\$0.21	n/a
Equity compensation plans not approved by stockholders - 2003			
Plan (2)	584,440	\$1.05	133,546
Equity compensation plans not approved by stockholders - 2004			
Plan (2)	371,403	\$2.57	2,109,496

- (1) Represent shares of common stock issuable outside of any stock option plan. The number of shares and exercise price have been adjusted to give effect to the EMLR - Hana Biosciences merger in July 2004 and the reincorporation effected in September 2004.
- (2) Represent shares issued under the Company's 2003 and 2004 Stock Option Plan. During 2004 the Company's Board of Directors adopted the 2004 Plan and all future issuances of securities will be made under the 2004 Plan. See also Note 4 of the Company's audited financial statements as of and for the year ended December 31, 2004 included in this prospectus.

### Stock Repurchases

We did not make any repurchases of our common stock during the fourth quarter of 2004.

### Regulation of Penny Stocks

Our common stock meets the definition of a "penny stock" under applicable SEC rules. Broker-dealers who sell penny stocks must satisfy several rules when recommending that their customers purchase penny stock. A summary of those rules is set forth below.

**Definition of a Penny Stock.** The SEC has adopted several rules regulating transactions involving "penny stocks." As a general matter, the term "penny stock" means any equity security other than a security

- that is a "reported security" as that term is defined by SEC rule, including securities listed on the Nasdaq Stock Market, the New York Stock Exchange or the American Stock Exchange,
- that is issued by an investment company,
- that is a put or call option issued by the Options Clearing House,
- that has a price of \$5.00 or more, *or*
- whose issuer has (i) net tangible assets of more than \$2 million if the issuer has been in business for at least 3 continuous years, and \$5 million if the issuer has been in business less than 3 years, (ii) average revenue of at least \$6 million for the last 3 years.

**Suitability Determination.** The SEC's rules governing penny stock transactions are designed to ensure that brokers and dealers make a determination that a particular customer is appropriately suited to purchase penny stocks. Accordingly, prior to the sale of a penny stock recommended by the broker-dealer to a new customer who is not an institutional accredited investor, the broker-dealer must approve the customer's account for transactions in penny stocks. The determination requires the broker-dealer to obtain from the customer information concerning the customer's "financial situation, investment experience, and investment objectives." Based on this information, the broker-

dealer must then reasonably determine that transactions in penny stocks are suitable for the customer and that the customer has sufficient knowledge and experience in financial matters that the person reasonably may be expected to be capable of evaluating the risks of penny stock transactions. The broker-dealer then must provide the customer with a written statement, to be signed by the customer, that sets forth the suitability determination made by the broker-dealer.

***Penny Stock Risk Disclosure Document.*** Prior to the initial penny stock transaction with a customer, the broker-dealer must provide to the customer a risk disclosure document, which states clearly that transactions in penny stocks can be very risky and urges the customer to use caution before proceeding with the transaction. The document warns the customer of the lack of liquidity in many penny stocks, the possibility of losing the investment, the need to use caution, and not to rely on the salesperson. The document also sets forth the remedies available to customers in the event the broker-dealer violates the penny stock rules in connection with a transaction with the customer. The risk disclosure document also includes pricing information relating to the penny stock and the compensation paid to the broker-dealer in connection with the transaction.

***Monthly Statements.*** The broker-dealer must also furnish to the customer a statement as of the last day of each month that describes for each penny stock held by the broker-dealer for the customer's account the price of the security, the number of shares of each penny stock security held for the customer, and the estimated market value of the security. The monthly statement must be sent to the customer within 10 days following the end of each month.

#### **USE OF PROCEEDS**

We will not receive any proceeds from the resale of any of the shares offered by this prospectus by the selling stockholders.



## SELLING STOCKHOLDERS

The following table sets forth the number of shares of the common stock owned by the selling stockholders as of April 25, 2005, and after giving effect to this offering.

Name	Shares beneficially owned before offering	Number of outstanding shares offered by selling stockholder	Number of shares offered by selling stockholder issued upon conversion of preferred stock	Percentage beneficial ownership after offering
------	--	---	---	---

### Shares Issued Upon Conversion of Series A Preferred Stock

Atlas Equity I, Ltd.	1,768,410 <sup>(1)</sup>	0	1,318,414	2.2
Bristol Investment Fund, Ltd.	333,786 <sup>(2)</sup>	0	274,415	--
McLaughlin III Limited Partnership(a)	84,604	0	84,604	--
David T. McLaughlin Revocable Trust	21,109	0	21,109	--
Arjun Gupta	70,503	0	70,503	--
Coqui Capital Partners, LP	1,004,538 <sup>(3)</sup>	0	168,871	3.5
Isaac Kier	1,004,538 <sup>(3)</sup>	0	42,217	3.5
JIJ Investments	1,004,538 <sup>(3)</sup>	0	42,217	3.5
Pearl Kier, as ttee under Revocable Trust FBO Pearl Kier	10,576	0	10,576	--
Cranshire Capital, L.P.(c)	47,039	0	47,039	--
ETP/FBR Venture Capital II, LLC (d)	379,958	0	379,958	--
Waterspout Investments Pte Ltd.	23,200 <sup>(4)</sup>	0	6,333	--
Matador Investments Pte Ltd.	23,220 <sup>(4)</sup>	0	12,665	--
Ramsay Investment PTE LTD	23,220 <sup>(4)</sup>	0	4,222	--
Millenium Partners, L.P. (e)	633,264	0	633,264	--
Shelia A Tomei and Thaddeus R. Tomei	1,410	0	1,410	--
Springvest Corporation (f)	116,483	0	116,483	--
<b>Subtotal</b>		<b>0</b>	<b>3,234,300</b>	

### Shares Issued in Hana Biosciences February 2004 Private Placement

Alfred Abraham	5,936	5,936	0	--
Sandra D. Anderson	29,685	29,685	0	--
Balanced Investment LLC (g)	43,938	43,938	0	--
Beck Family Partners, L.P. (h)	29,685	29,685	0	--
Sam Belzberg	29,685	29,685	0	--
Biocom Management & Investments (2002) Ltd. (i)	14,842	14,842	0	--
Brino Investment Ltd. (j)	16,921	16,921	0	--
Bristol Investment Fund, Ltd.	333,786 <sup>(2)</sup>	59,371	0	--
Chicago Private Investments, Inc. (k)	14,842	14,842	0	--
Adam J. Chill	14,806	14,806	0	--
Alan Clingman	14,842	14,842	0	--
Dylan Colby	14,842	14,842	0	--
Ivette & Isaac Dabah 2002 Trust	29,685	29,685	0	--
Ytzhak Dankner	14,842	14,842	0	--

Edmund A. Debler	14,842	14,842	0	--
Delaware Charter Guaranty & Trust Company fbo Mark Berg IRA	105,755	105,755	0	--
Domeco Venture Capital Fund (I)	14,842	14,842	0	--

Name	Shares beneficially owned before offering	Number of outstanding shares offered by selling stockholder	Number of shares offered by selling stockholder issued upon conversion of preferred stock	Percentage beneficial ownership after offering
Isaac R. Dweck	52,371	52,371	0	--
Robert I. Falk	14,842	14,842	0	--
Far Ventures (m)	14,842	14,842	0	--
Fiserv Securities Inc. A/C/F Ronald M. Lazar IRA	14,842	14,842	0	--
Fiserv Securities Inc. A/C/F Anthony G. Polak IRA	14,842	14,842	0	--
Howard Gittis	59,372	59,372	0	--
Jacob Gottlieb	1,768,410 <sup>(1)</sup>	59,371	0	2.2
Arjun Gupta	218,930	148,427	0	--
Neil Herskowitz	14,842	14,842	0	--
Joseph Hickey	29,685	29,685	0	--
Peter Kash	172,176	59,371	0	*
Ivan Kaufman Grantor Retained Annuity Trust	29,685	29,685	0	--
Bonnie B. Kazam	29,686	29,686	0	--
Dr. Daniel Kessel	14,842	14,842	0	--
Lawrence & Shirley Kessel	14,842	14,842	0	--
Howard Kessler	14,842	14,842	0	--
Keys Foundation (n)	141,007	141,007	0	--
Kier Family L.P.	1,004,538 <sup>(3)</sup>	118,742	0	3.5
Ralph Kier	14,842	14,842	0	--
Robert Klein & Myriam Gluck JTRS	14,842	14,842	0	--
Steven Koffman	14,842	14,842	0	--
Larich Associates (o)	14,842	14,842	0	--
Adam S. Leeds, Successor Trustee FBO Bertha Leeds U/A/D 1/23/81	14,842	14,842	0	--
Bruce H. Lipnick	14,842	14,842	0	--
Steve Lisi	14,842	14,842	0	--
J. Jay Lobell	74,213	74,213	0	--
Harris RL Lydon, Jr.	14,842	14,842	0	--
William R. McLaughlin	14,101	14,101	0	--
Fred Mermelstein	14,101	14,101	0	--
Wayne W. Mills	14,101	14,101	0	--
Michael A. Mullen	14,806	14,806	0	--
Renato Negrin	14,842	14,842	0	--
Susan and Harry Newton JTWROS	29,686	29,686	0	--
PCG Tagi (Series N), LLC (p)	282,456	282,456	0	--
Premero Investments Ltd. (q)	14,842	14,842	0	--
RL Capital Partners, L.P. (s)	44,527	44,527	0	--
Mark H. Rachesky	29,686	29,686	0	--
Elke R. de Ramirez	15,440	15,440	0	--
Riverside Contracting LLC (t)	14,842	14,842	0	--
Lyon Roth	14,842	14,842	0	--



Name	Shares beneficially owned before offering	Number of outstanding shares offered by selling stockholder	Number of shares offered by selling stockholder issued upon conversion of preferred stock	Percentage beneficial ownership after offering
Howard Schain	14,842	14,842	0	--
Andrew W. Schonzeit	14,842	14,842	0	--
Kellie Seringer	14,842	14,842	0	--
South Ferry #2 L.P.	237,485 <sup>(5)</sup>	222,791	0	--
Speisman Family 2000 Ltd. Partnership(u)	14,842	14,842	0	--
Edward L. Steinberg	14,842	14,842	0	--
Ari J. Storch	14,806	14,806	0	--
Gary J. Strauss	47,502	44,527	0	--
Reuben Taub	14,842	14,842	0	--
Tisu Investment Ltd. (n)	22,561	22,561	0	--
Joseph J. Vale	29,685	29,685	0	--
Stephan P. & Barbara T. Vermut Trust Dated 3/02	29,685	29,685	0	--
Hillel Weinberger	29,752	29,752	0	--
David Wilstein & Susan Wilstein, ttees of the Century Trust dtd 12/19/94	14,842	14,842	0	--
David Wilstein & Susan Wilstein, ttees of the Denise Wilstein Trust dtd 12/19/94	14,842	14,842	0	--
Aaron Wolfson	237,485 <sup>(5)</sup>	14,694	0	--
<b>Subtotal</b>		<b>2,554,672</b>		
<b>Miscellaneous Outstanding Common Shares</b>				
R&R Biotech, LLC (v)	1,378,974	1,378,974	0	--
Chase Financing, Inc. (x)	172,371	172,371	0	--
<b>Subtotal</b>		<b>1,551,345</b>	<b>0</b>	
<b>TOTALS</b>		<b>4,106,017</b>	<b>3,234,300</b>	

\* Less than 1%.

- (a) C. Jay McLaughlin is president of the general partner of McLaughlin Limited Partnership and has voting and dispositive control over the shares held by such selling stockholder.
- (c) Mitchell P. Kopin, President of Downview Capital and General Partner of Cranshire Capital, L.P., holds voting and dispositive control over the shares held by Cranshire Capital, L.P.
- (d) Wei-Wu He holds voting and/or dispositive control over the shares held by the selling stockholder.
- (e) Edmund Debler holds voting and dispositive control over the shares held by Millenium Partners, L.P.
- (f) Bruce Hsiang holds voting and/or dispositive control over the shares held by the selling stockholder.
- (g) Alonso B. Diaz is investment adviser and holds voting and dispositive control over the shares held by Balanced Investments LLC.
- (h) Ronald Beck is the general partner of Beck Family Partners, L.P. and voting and dispositive control over the shares held by the limited partnership.
- (i) Mony Ben Dor is a managing partner of Biocom Management & Investments (2002) Ltd and has voting and dispositive control over the shares held by the selling stockholder.
- (j) Bruno Widmer is the sole shareholder of the selling stockholder.
- (k) Linda Gallenberger holds voting and dispositive power over the shares held by the selling stockholder.

- (l) Jack Polak is the general partner of Domeco Venture Capital Fund and voting and dispositive control over the shares held by the selling shareholder.
- (m) Steven M. Farber and S. Edmund Farber are partners of Far Ventures, a general partnership.
- (n) Tis Prager holds voting and dispositive control over the shares held by the selling shareholder.
- (o) Lawrence R. Gross is a partner of Larish Associates and holds voting and dispositive control over the shares held by the selling shareholder.
- (p) Gregg Ritchie has voting and/or dispositive control over the shares held by the selling stockholder.
- (q) Yair Green is managing director of Premero Investments Ltd and holds voting and dispositive control over the shares held by the selling shareholder.
- (s) Ronald Lazar is managing member of the general partnership of RL Capital Partners, L.P. and holds voting and dispositive control over the shares held by the selling shareholder.
- (t) Neil Herskowitz holds voting and dispositive control over the shares held by the selling shareholder.
- (u) Aaron Speisman holds voting and/or dispositive control over the shares held by the selling stockholder.
- (v) Thomas Pinou holds voting and dispositive control over the shares held by the selling stockholder.
- (x) Robert Herskowitz holds voting and dispositive control over the shares held by the selling stockholder. The selling stockholders is not affiliated with or related to JP Morgan Chase Bank or its affiliates.

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- (1) Represents 1,710,496 common shares held by Atlas Equity I, Ltd., including 90,480 shares issuable upon the exercise of a warrant, and 59,371 common shares held by Jacob Gotlieb. Mr. Gotlieb has voting and investment power over the shares held by Atlas Equity I, Ltd.
  - (2) Includes 274,415 common shares issuable upon conversion of 194,611 shares of Series A Preferred Stock. Paul Kessler has voting and dispositive control over the shares held by Bristol Investment Fund.  
Represents (a) 282,014 shares of common stock held by Coqui Capital Partners, L.P., of which 168,871 shares are issuable upon conversion of 200,000 shares of Series A Preferred Stock; (b) 118,742 shares of common stock held by Kier Family Partners, L.P.; (c) 42,217 shares of common stock issuable upon conversion of 29,940 shares of Series A Preferred Stock held by JIJ Investments; and (d)
  - (3) 42,217 shares of common stock issuable upon conversion of 29,940 shares of Series A Preferred Stock held directly by Mr. Kier. Mr. Kier is general partner of both Coqui Capital Partners and Kier Family Partners and is a partner in JIJ Investments, a partnership. In addition to Mr. Kier, Coqui Capital Partners LP, Kier Family L.P. and JIJ Investments are all selling stockholders. Mr. Kier is a director of our company.  
Each of Caribbean American LTD, Inter-American Securities LTD I and Ramsay Investment PTE LTD are affiliates of Coutts Trustees
  - (4) (Switzerland) SA. The total shares beneficially held by each of the foregoing selling stockholders includes the shares held in the name of such related entities. Katherine Litau-Kutch holds voting and/or dispositive control over the shares held by these selling stockholders.
  - (5) Represents 222,791 shares held by South Ferry #2 L.P. and 14,694 shares held by Aaron Wolfson. Mr. Wolfson is the general partner of South Ferry #2 L.P.

## PLAN OF DISTRIBUTION

We are registering the shares offered by this prospectus on behalf of the selling stockholders. The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities

which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).



The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

Because of its affiliation with a broker-dealer, R&R Biotech, LLC, a selling stockholder, is deemed to be an underwriter in connection with the offering of its shares under this prospectus. Other selling shareholders might be, and any broker-dealers that act in connection with the sale of securities will be, deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals will be deemed to be underwriting discounts or commissions under the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement that includes this prospectus effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold pursuant to Rule 144(k) of the Securities Act.

## DESCRIPTION OF CAPITAL STOCK

### General

Our certificate of incorporation, as amended to date, authorizes us to issue up to 100,000,000 shares of common stock, par value \$.001 per share, and 10,000,000 shares of preferred stock, par value \$.001 per share. As of April 25, 2005, we have no shares of preferred stock outstanding. As of April 25, 2005, we had 17,923,216 shares of common stock issued and outstanding. The transfer agent and registrar for our common stock is Corporate Stock Transfer, Denver Colorado.

### Common Stock

Holders of our common stock are entitled to one vote for each share on all matters to be voted on by our stockholders. Holders of our common stock do not have any cumulative voting rights. Common stockholders are entitled to share ratably in any dividends that may be declared from time to time on the common stock by our board of directors from funds legally available for dividends. Holders of common stock do not have any preemptive right to purchase shares of common stock. There are no conversion rights or sinking fund provisions for our common stock.

## **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Pursuant to our certificate of incorporation and bylaws, we may indemnify an officer or director who is made a party to any proceeding, because of his position as such, to the fullest extent authorized by the Colorado Business Corporation Act, as the same exists or may hereafter be amended. In certain cases, we may advance expenses incurred in defending any such proceeding.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

### **ABOUT THIS PROSPECTUS**

This prospectus is not an offer or solicitation in respect to these securities in any jurisdiction in which such offer or solicitation would be unlawful. This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (SEC File No. 333-118426). The registration statement that contains this prospectus (including the exhibits to the registration statement) contains additional information about our company and the securities offered under this prospectus. That registration statement can be read at the SEC web site or at the SEC's offices mentioned under the heading "Where You Can Find More Information." We have not authorized anyone else to provide you with different information or additional information. You should not assume that the information in this prospectus, or any supplement or amendment to this prospectus, is accurate at any date other than the date indicated on the cover page of such documents.

### **WHERE YOU CAN FIND MORE INFORMATION**

Federal securities law requires us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, proxy statements and other information with the SEC. You can inspect and copy this information at the Public Reference Facility maintained by the SEC at Judiciary Plaza, 450 5<sup>th</sup> Street, N.W., Room 1024, Washington, D.C. 20549. You can receive additional information about the operation of the SEC's Public Reference Facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding companies that, like us, file information electronically with the SEC.

### **VALIDITY OF COMMON STOCK**

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Maslon Edelman Borman & Brand, LLP, Minneapolis, Minnesota.

## EXPERTS

The financial statements of Hana Biosciences, Inc. (formerly Hudson Health Sciences, Inc.) as of December 31, 2004 and 2003, and for the years then ended and for the period from December 6, 2002 (date of inception) to December 31, 2004 included in this prospectus, have been included herein in reliance on the report, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, of J.H. Cohn LLP, independent registered public accounting firm, given on the authority of that firm as experts in accounting and auditing.

## CHANGES IN CERTIFYING ACCOUNTANT

Following the July 2004 merger transaction between Hana Biosciences, Inc. and Email Real Estate.com, Inc., in which Hana Biosciences was the acquiror for accounting purposes, we determined to change the independent registered public accounting firm that had been engaged by Email Real Estate.com. Accordingly, on August 11, 2004, we dismissed James E. Scheifley & Associates, P.C. as the independent registered public accounting firm of Email Real Estate.com. Our Board of Directors participated in and approved the decision to change public accountants. The reports of James E. Scheifley & Associates, P.C. on the financial statements of Email Real Estate.com, Inc. for the two most recently completed fiscal years contained no adverse opinion or disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope, or accounting principle. In connection with its audit for the two most recent fiscal years and through August 11, 2004, there have been no disagreements with James E. Scheifley & Associates, P.C. on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements if not resolved to the satisfaction of James E. Scheifley & Associates, P.C. would have caused them to make reference thereto in its report on the financial statements for such years. During the most recent fiscal year and through August 11, 2004, none of the events specified in Item 304(a)(iv)(B) of Regulation S-B promulgated by the SEC have occurred. We requested that James E. Scheifley & Associates, P.C. furnish a letter addressed to the SEC stating whether or not it agreed with the above statements. A copy of such letter was filed as an exhibit to our Form 8-K/A filed with the SEC on September 1, 2004.

On August 11, 2004, Email Real Estate.com, Inc. engaged J.H. Cohn LLP to be its independent registered public accounting firm. During the two most recent fiscal years and to August 11, 2004, Email Real Estate.com had not consulted with J.H. Cohn LLP regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the company's financial statements, and either a written report was provided to the Registrant or oral advice was provided that J.H. Cohn LLP concluded was an important factor considered by the company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was the subject of a disagreement and required to be reported under Item 304(a)(1)(iv) of Regulation S-B and the related instructions thereto.

**Index to Financial Statements of  
Hana Biosciences, Inc.**

**Audited Financial Statements:**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
Hana Biosciences, Inc.

We have audited the accompanying balance sheets of Hana Biosciences, Inc. (A Development Stage Enterprise) as of December 31, 2004 and 2003, and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for the years then ended and for the period from December 6, 2002 (date of inception) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Hana Biosciences, Inc. (A Development Stage Company) as of December 31, 2004 and 2003, and the results of its operations and cash flows for the years then ended and for the period from December 6, 2002 (date of inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and its operating activities have used cash since the Company's inception. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

/s/ J.H. Cohn LLP

San Diego, California  
January 20, 2005

**HANA BIOSCIENCES, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**

**BALANCE SHEETS**

	<u>December 31, 2003</u>	<u>December 31, 2004</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$87,675	\$6,584,361
Prepaid expenses	9,914	26,885
Total current assets	97,589	6,611,246
Property and equipment, net	44,396	109,604
Investments in restricted equity securities, at cost	—	636,000
Other assets	20,203	20,303
Total assets	<u>\$162,188</u>	<u>\$7,377,153</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$108,313	\$649,644
Accrued expenses	—	515,215
Total current liabilities	108,313	1,164,859
Notes payable to stockholders	676,619	—
Accrued interest payable	12,879	—
Total liabilities	<u>797,811</u>	<u>1,164,859</u>
Commitments and contingencies		
Stockholders' equity (deficiency):		
Preferred stock; \$0.001 par value:		
10,000,000 shares authorized, 0 and 2,395,210 shares issued and outstanding at December 31, 2003 and December 31, 2004, respectively (liquidation preference \$8,000,000)		
	—	2,395
Common stock; \$0.001 par value:		
100,000,000 shares authorized, 5,640,266 and 10,792,702 shares issued and outstanding at December 31, 2003 and December 31, 2004, respectively		
	5,640	10,793
Additional paid-in capital	55,063	13,975,514
Common stock to be issued - 55,500 shares	—	249,750
Deficit accumulated during the development stage	(696,326 )	(8,026,158 )
Total stockholders' equity (deficiency)	<u>(635,623 )</u>	<u>6,212,294</u>
Total liabilities and stockholders' equity (deficiency)	<u>\$162,188</u>	<u>\$7,377,153</u>

See accompanying notes to financial statements.





**HANA BIOSCIENCES, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**

**STATEMENTS OF OPERATIONS**

	Years Ended December 31,		Cumulative Period from December 6, 2002 (date of inception) to December 31,
	2003	2004	2004
Operating expenses:			
General and administrative	\$229,601	\$2,808,706	\$3,040,372
Research and development	309,376	4,546,519	4,998,300
Total operating expenses	538,977	7,355,225	8,038,672
Loss from operations	(538,977 )	(7,355,225 )	(8,038,672 )
Other income (expense):			
Interest income (expense), net	(12,879 )	26,040	13,161
Other income (expense), net	—	(647 )	(647 )
Total other income (expense)	(12,879 )	25,393	12,514
Net loss	\$(551,856 )	\$(7,329,832 )	\$(8,026,158 )
Net loss per share, basic and diluted	\$(0.10 )	\$(0.80 )	
Weighted average shares used in computing net loss per share, basic and diluted	5,640,271	9,119,344	

See accompanying notes to financial statements.

**HANA BIOSCIENCES, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)**

Period from December 6, 2002 (date of inception) to December 31, 2004

	<u>Preferred stock</u>		<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Common Stock to be Issued</u>	<u>Subscription receivable</u>	<u>Unearned consulting fee</u>	<u>Deficit accumulated during development stage</u>	<u>Total stockholder equity (deficiency)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>						
Issuance of common stock at \$0.001 per share for subscription receivable		\$—	5,640,266	\$5,640	\$34,360	\$—	\$(40,000)	\$—	\$—	\$—
Net loss	—	—	—	—	—	—	—	—	(144,470)	(144,470)
Balance at December 31, 2002			5,640,266	5,640	34,360	—	(40,000)	—	(144,470)	(144,470)
Payment for subscription receivable	—	—	—	—	—	—	4,000	—	—	4,000
Satisfaction of subscription receivable through rendering of services	—	—	—	—	—	—	36,000	—	—	36,000
Stock options issued to nonemployees for services	—	—	—	—	14,750	—	—	—	—	14,750
Common stock to be issued for services rendered	—	—	—	—	5,953	—	—	—	—	5,953
Net loss	—	—	—	—	—	—	—	—	(551,856)	(551,856)

Balance at December 31, 2003	—	—	5,640,266	5,640	55,063	—	—	—	(696,326 )	(635,623
Common stock issued for services to be rendered			126,131	126	212,319	—	—	(212,445 )	—	—
Common stock issued for services rendered in 2003	—	—	3,887	4	591	—	—	—	—	595
Proceeds from private placement, net of \$341,979 fees	—	—	2,802,989	2,803	4,376,352	—	—	—	—	4,379,155
Stock options issued to nonemployees for services	—	—	—	—	310,252	—	—	—	—	310,252
Compensation expense recorded upon issuance of stock options to employees	—	—	—	—	375,552	—	—	—	—	375,552
Proceeds from private placement	2,395,210	2,395	—	—	7,997,605	—	—	—	—	8,000,000
Issuance of shares for debt repayment	—	—	63,326	64	149,936	—	—	—	—	150,000
Issuance of shares for license agreement	—	—	73,121	73	499,927	—	—	—	—	500,000
55,500 shares to be issued for services rendered	—	—	—	—	—	249,750	—	—	—	249,750
Shares issued by accounting acquirer in reverse acquisition	—	—	2,082,982	2,803	(2,083 )	—	—	—	—	—

Satisfaction of unearned consulting fees through rendering of services	—	—	—	—	—	—	—	212,445	—	212,445
Net loss			—	—	—	—	—	—	(7,329,832 )	(7,329,832 )
Balance at December 31, 2004	<u>2,395,210</u>	<u>\$ 2,395</u>	<u>10,792,702</u>	<u>\$10,793</u>	<u>\$13,975,514</u>	<u>\$ 249,750</u>	<u>\$ —</u>	<u>\$—</u>	<u>\$(8,026,158 )</u>	<u>\$6,212,294</u>

See accompanying notes to financial statements.

**HANA BIOSCIENCES, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**

**STATEMENTS OF CASH FLOWS**

	Year Ended		Cumulative
	December 31,		Period from
	2003	2004	December 6, 2002 (date of inception) to December 31, 2004
<b>Cash flows from operating activities:</b>			
Net loss	\$(551,856 )	\$(7,329,832 )	\$(8,026,158 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,933	21,093	26,026
Issuance of options to employees	—	375,552	375,552
Issuance of stock and options to nonemployees for services	20,703	310,847	331,550
Services rendered for satisfaction of unearned consulting fee	—	212,445	212,445
Services rendered in lieu of payment of subscription receivable	36,000	—	36,000
Shares to be issued to employees for services rendered	—	249,750	249,750
Issuance of shares in partial consideration for license agreement	—	500,000	500,000
Changes in operating assets and liabilities:			
Increase in prepaid expenses and other assets	(30,117 )	(17,071 )	(47,188 )
Increase (decrease) in accounts payable	(5,200 )	541,331	649,644
Increase in accrued and other current liabilities	12,879	502,336	515,215
Net cash used in operating activities	(512,658 )	(4,633,549 )	(5,177,164 )
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(49,329 )	(86,301 )	(135,630 )
Purchase of equity securities	—	(636,000 )	(636,000 )
Net cash used in investing activities	(49,329 )	(722,301 )	(771,630 )
<b>Cash flows from financing activities:</b>			
Proceeds from issuances of notes payable to stockholders	645,662	125,000	801,619
Collection of subscription receivable	4,000	—	4,000
Repayment of notes payable to stockholders	—	(651,619 )	(651,619 )
Proceeds from private placements of preferred and common stock, net	—	12,379,155	12,379,155
Net cash provided by financing activities	649,662	11,852,536	12,533,155
Net increase in cash and cash equivalents	87,675	6,496,686	6,584,361
Cash and cash equivalents, beginning of period	—	87,675	—

Cash and cash equivalents, end of period	<u>\$87,675</u>	<u>\$6,584,361</u>	<u>\$6,584,361</u>
Supplemental disclosures of cash flow data:			
Cash paid for interest	<u>—</u>	<u>\$37,749</u>	<u>\$37,749</u>
Supplemental disclosures of noncash financing activities:			
Common stock issued for repayment of debt	<u>—</u>	<u>\$150,000</u>	<u>\$150,000</u>

See accompanying notes to financial statements.

**HANA BIOSCIENCES, INC.**  
**(A Development Stage Company)**  
**NOTES TO FINANCIAL STATEMENTS**  
**December 31, 2004**

NOTE 1. BUSINESS DESCRIPTION AND BASIS OF PRESENTATION

**BUSINESS:**

Hana Biosciences, Inc. ("Hana" or the "Company") is a biopharmaceutical company based in South San Francisco, California, which seeks to acquire, develop, and commercialize innovative products to enhance cancer care. The Company has secured research grants of approximately \$12 million to fund the initial development of each of its two initial products. The Company is committed to creating value by accelerating the development of lead product candidates and expanding its product candidate pipeline by being the alliance partner of choice to universities, research centers and other institutions.

**BASIS OF PRESENTATION:**

The Company is a development stage enterprise since the Company has not generated revenue from the sale of its products and its efforts through December 31, 2004 have been principally devoted to identification, licensing and clinical development its products as well as raising capital. Accordingly, the financial statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises."

The Company reported a net loss of \$7,329,832 for the year ended December 31, 2004. The net loss from date of inception, December 6, 2002, to December 31, 2004, amounted to \$8,026,158. The Company's operating activities have used cash since its inception. These matters raise substantial doubt about the Company's ability to continue as a going concern.

The Company has financed operations since inception primarily through equity and debt financing. During the year ended December 31, 2004, the Company had a net increase in cash and cash equivalents of \$6,496,686. This increase primarily resulted from net cash provided by financing activities of \$11,852,536, substantially all of which was derived from the Company's two private placements which netted the Company \$12,379,155. The increase in cash provided by financing activities was offset by net cash used in operating activities of \$4,633,549 and net cash used in investing activities of \$722,301 for the year ended December 31, 2004. Total cash resources as of December 31, 2004 was \$6,584,361 compared to \$87,765 at December 31, 2003.

Continued operations will depend on whether the Company is able to raise additional funds through various potential sources, such as equity and debt financing. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that the Company obtains will be sufficient to meet needs in the long term. Through December 31, 2004, a significant portion of the Company's financing has been through private placements of common stock, preferred stock and debt financing. Hana will continue to fund operations from cash on hand and through the similar sources of capital previously described. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet future needs. Although we expect to have sufficient cash to fund our operations through 2005, this would require a significant reduction in the pace of our three ongoing clinical trials. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that we will need to raise additional capital in 2005, likely by selling shares of our capital stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. The Company will need additional financing thereafter until it can achieve profitability, if ever.

NOTE 2. MERGER WITH PUBLIC COMPANY AND REINCORPORATION

In July 2004, the Company merged with Email Real Estate.com, Inc., or “EMLR,” a Colorado corporation. In connection with that transaction, a wholly-owned subsidiary of EMLR merged with and into the Company, with the Company remaining as the surviving corporation and a wholly-owned subsidiary of EMLR. The Company then changed its name to “Hana Biosciences, Inc.” in connection with the merger. In exchange for their shares of capital stock in Hana Biosciences, the former stockholders of Hana Biosciences received shares of capital stock of EMLR representing approximately 87 percent of the outstanding equity of EMLR on a fully-diluted basis after giving effect to the transaction. In addition, the terms of the merger provided that the board of directors of EMLR would be reconstituted immediately following the effective time of the transaction such that the directors of EMLR were replaced by the directors of Hana Biosciences. Further, upon the effective time of the merger, the business of EMLR, which was insignificant, was abandoned and the business plan of Hana Biosciences was adopted. The transaction was therefore accounted for as a reverse acquisition with Hana Biosciences, Inc. as the acquiring party for purposes and EMLR as the acquired party for accounting purposes. Accordingly, the 2,082,982 shares of EMLR outstanding at the time of the merger were deemed, for accounting purposes, to be an issuance by the Company. The merger with EMLR did not have any significant effects on the Company’s assets or liabilities or on the Company’s result of operations subsequent to the date of the merger.

At a special meeting held on September 28, 2004, the shareholders of EMLR approved a proposal to reincorporate that corporation, then the parent corporation of Hana Biosciences, under the laws of the state of Delaware by merging it with and into Hana Biosciences, a Delaware corporation, so that Hana Biosciences remained as the surviving corporation. The reincorporation merger became effective September 30, 2004. In connection with the reincorporation merger, each outstanding common share of EMLR automatically converted into and became exchangeable for one twelfth of a share of common stock of Hana Biosciences. In addition, each of the 6,179,829 outstanding shares of EMLR, Series B Convertible Preferred Stock automatically converted into approximately 1.410068 common shares of Hana Biosciences. Accordingly, all share and per share information in these financial statements are presented to retroactively reflect the reincorporation and the effect it had on the capitalization of the Company.

Unaudited pro forma information, assuming this acquisition occurred at the beginning of the respective years ended December 31, 2003 and 2004 is as follows:

	<u>2003</u>	<u>2004</u>
Net loss	\$(636,856 )	\$(7,332,832 )
Net loss per share, basic and diluted	<u>\$(0.11 )</u>	<u>\$(0.80 )</u>

### NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

#### RESEARCH AND DEVELOPMENT

All research and development costs are expensed as incurred and include costs of consultants who conduct research and development on behalf of the Company. Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.



## INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

## COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period (there were no adjustments to net loss since there were no requirements to pay dividends on outstanding preferred stock). Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect because the Company incurred a net loss during each period presented. The number of shares potentially issuable at December 31, 2003 and 2004 upon exercise or conversion that were not included in the computation of net loss per share totaled 556,997 and 2,537,086, respectively. In addition, on January 18, 2005 the Securities and Exchange Commission declared effective the Company's registration statement on Form SB-2 (see Note 13). As a result, all Series A Convertible Preferred Stock automatically converted into an aggregate of 3,377,409 common shares which will affect the basic and dilutive earnings per share calculation beginning in the year ending December 31, 2005.

## PROPERTY AND EQUIPMENT

Property and equipment is recorded at cost and depreciated using the straight-line method over the estimated useful life of 3 to 5 years for the assets. Property and equipment consists of the following at December 31:

	2003	2004
Property and equipment	\$49,329	\$ 135,630
Less accumulated depreciation	(4,933 )	(26,026 )
Net property and equipment	<u>\$44,396</u>	<u>\$ 109,604</u>

## CONCENTRATIONS OF CREDIT RISK

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash and cash equivalent balances primarily in one high credit quality financial institution. As of December 31, 2004, the balance exceeded the Federal Deposit Insurance Corporation limitation for coverage of \$100,000 by approximately \$6,590,000.

## STOCK OPTIONS

The Company measures compensation cost related to stock options issued to employees using the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees". The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Principles No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation" and Statement of Financial Accounting Principles No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure". During the year ended December 31, 2004, the Company recorded earned compensation cost of \$375,552 attributable to the intrinsic value of options granted to employees. This cost was recognized in the accompanying financial statements for the stock options granted by the Company to its employees since all of those options have been granted at exercise prices that were less than the market value at the date of grant.

For the year ended December 31, 2003 there was no material difference between the Company's historical net loss and pro forma net loss, determined using the Black-Scholes option pricing model in accordance with the provisions of SFAS 123.

Had compensation costs for the year ended December 31, 2004 been determined in accordance with the fair value method prescribed by SFAS 123 for all options issued to employees and amortized over the vesting period, the Company's net loss applicable to common shares and net loss per common share (basic and diluted) for options would have been increased to the pro forma amounts indicated below.

	2004
Net loss, as reported	\$(7,329,832 )
Add: Stock-based employee compensation expense for stock options included in reported net loss per common share	375,552
Deduct: Total stock-based employee compensation expense determined under fair value method	<u>(468,863 )</u>
Net loss, pro forma	<u><u>\$(7,423,143 )</u></u>
Net loss per common share - basic	
As reported	<u><u>\$(0.80 )</u></u>
Pro forma	<u><u>\$(0.81 )</u></u>

As a result of amendments to SFAS 123, the Company will be required to expense the fair value of employee stock options over the vesting period beginning with its fiscal quarter ending March 31, 2006.

In accordance with the provisions of SFAS 123, all other issuances of common stock, stock options or other equity instruments to non-employees as the consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). During the year ended December 31, 2003 and 2004, the Company recognized \$14,750 and \$310,252 of expense relating to the granting of options to non-employees for services and such expense is included in the accompanying statement of operations, respectively. The value of the options granted in 2003 was determined using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 0%, risk-free interest rate of 3.0%; and expected lives of ten years. The value of the options granted in 2004 was determined using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 0% for all options granted before July 21 2004 and 89% - 95% for options granted after July 21, 2004, risk-free interest rate of 3.0%; and expected lives of eight to ten years.

#### CASH AND CASH EQUIVALENTS

The Company considers all highly-liquid investments with maturities of three months or less when acquired as cash equivalents.

In accordance with the provisions of Statement of Financial Accounting Standards No. 115 "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115), the Company has recorded its restricted investment in equity securities under the cost method.

#### NOTE 4. STOCKHOLDERS' EQUITY

##### Issuance of common stock:

On December 6, 2002, the Company issued 5,640,266 shares of its common stock to various private investors for subscriptions receivable of \$40,000 (\$0.14 per share). These receivables were relieved in 2003 through a cash payment of \$4,000 and various services rendered amounting to \$36,000.

On January 30, 2004, the Company issued 3,887 shares of common stock valued at \$6,548 (\$1.68 per share) to a vendor in return for services rendered in 2003.

On February 19, 2004, the Company sold 2,802,989 shares of common stock at \$1.68 per share during a private placement. The Company raised net proceeds of approximately \$4.4 million (see Note 5).

On January 31 and June 1, 2004, the Company entered into two separate agreements to issue an aggregate of 267,734 shares of common stock valued at \$450,948 (\$1.68 per share) to two vendors in return for services to be rendered. On December 31, 2004 an amendment was reached with one of the vendors to reduce the amount ultimately issuable in common stock for services already performed. As a result, the Company issued 126,131 shares of common stock valued at \$212,445 (\$1.68 per share) to two vendors in return for services rendered during 2004. The Company is no longer obligated to issue any additional shares in accordance with these two agreements.

On August 18, 2004, the Company issued 63,326 shares of common stock valued at \$150,000 (\$2.37 per share) for repayment of outstanding notes payable.

On November 3, 2004, the Company issued 73,121 shares of common stock valued at \$500,000 (\$6.84 per share) in satisfaction of the Company's newly signed license agreement with NovaDel Pharma, Inc (see Note 6).

##### Issuance of Series A Convertible Preferred Stock:

The Company is authorized to issue up to 10,000,000 shares of preferred stock.

On July 21, 2004, the Company sold 2,395,210 shares of Series A Convertible Preferred Stock at \$3.34 per share in a private placement. The Company raised gross proceeds of \$8.0 million. Each share of Series A Convertible Preferred Stock was convertible at the holder's election into 1.410068 common shares. On January 18, 2005, upon the effective date of the registration statement covering the resale of the common shares issuable upon conversion of the Series A Preferred Stock, each share of Series A Preferred Stock automatically converted into common shares (see Note 13).

Along with the holders of common stock, each holder of Series A shares had one vote on all matters submitted to the holders of common stock for each share of common stock into which the Series A shares could be converted.

Upon the liquidation, dissolution or winding up of our company, whether voluntary or involuntary, the holders of the Series A shares would have been entitled to be paid, prior to any payments made to the holders of any securities ranking junior to the Series A shares, including common stockholders, an amount equal to \$3.34 per share. Holders of Series A shares were not entitled to dividends.

#### Stock Options:

During 2003, the Company established a stock option plan (the "2003 Plan") under which it may grant incentive and non-qualified stock options to employees, directors, consultants and service providers to purchase up to an aggregate of 1,000,000 shares of its common stock at an exercise price determined by a committee of the Board of Directors subject to the following: (a) the exercise price of an incentive option shall not be less than 100% of fair market value of the common stock at the date of the grant; and (b) the exercise price of a non-qualified option shall be determined by the committee. As of December 31, 2003, the Company had not issued any options under the 2003 Plan and as of December 31, 2004, 866,454 options have been issued under the 2003 plan.

During the year ended December 31, 2003, the Company recognized \$14,750 of expense relating to the granting of options to non-employees for services and such expense is included in the accompanying statement of operations. The value of the options granted in 2003 was determined using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 0%, risk-free interest rate of 3.0%; and expected lives of ten years. Options were granted to employees at fair value.

During 2003, the Company granted options to purchase 556,977 shares of common stock outside the 2003 Plan to employees and outside consultants of the Company at a weighted average exercise price of \$0.24 per share.

During 2004, the Company established a new stock option plan (the "2004 Plan") under which it may grant incentive and non-qualified stock options to employees, directors, consultants and service providers to purchase up to an aggregate of 2,500,000 shares of its common stock at an exercise price determined by a committee of the Board of Directors. As of December 31, 2004, the Company had issued 390,504 options under the 2004 Plan.

During the year ended December 31, 2004, the Company granted options to purchase an aggregate of 1,478,815 shares of common stock to employees and directors of the Company. These options were granted at a weighted average exercise price of \$1.16 per share. During the year ended December 31, 2004, the Company issued options to certain employees where the fair value exceeded the exercise price. The Company expensed \$375,552 in 2004 relating to the intrinsic value associated with the option grants.

During the year ended December 31, 2004, the Company granted options to purchase an aggregate of 399,822 shares of common stock to vendors, members of the Scientific Advisory Board and license agreement partners. These options were granted at a weighted average exercise price of \$1.00. The fair value of these options was determined to be \$302,002 on the date of the grant using the Black-Scholes option pricing model using the following assumptions: dividend yield of 0%; expected volatility of 0% for all options granted before July 21 2004 and 89% - 95% for options granted after July 21, 2004; risk-free interest rate of 3.0%; and expected lives of eight to ten years. Also, the Company incurred \$8,250 of expense in 2004 relating to options issued in 2003 and vesting in the current year.

The weighted average fair value of options granted during 2003 and 2004 is as follows:

	2003	2004
Exercise price equal to market price for 0 and 535,826 shares	\$ --	\$0.36
Exercise price less than market price for 521,725 and 1,286,409 shares	\$ 0.71	\$2.48
Exercise price greater than market price for 35,252 and 56,402 shares	\$ 0.00	\$0.00

The following table summarizes information about stock options outstanding at December 31, 2003 and 2004, all of which are at fixed prices:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding January 1, 2003	0	\$0.00
Options granted under the plan	0	0.00
Options granted outside the plan	556,977	0.24
Options exercised	0	0.00
Options cancelled	0	0.00
Outstanding December 31, 2003	556,977	0.24
Options granted under the plan	1,256,958	1.56
Options granted outside the plan	621,679	0.24
Options exercised	0	0.00
Options cancelled	(176,259)	0.39
Outstanding December 31, 2004	2,259,355	0.97
Exercisable at December 31, 2004	592,531	0.80

The following table summarizes information about stock options outstanding at December 31, 2004:

Exercise Price	Weighted Average Number of Options Outstanding	Remaining Contractual Life of Options Outstanding	Number of Options Exercisable
\$ 0.07	112,808	9.2 yrs.	112,808
\$ 0.17	678,079	8.9 yrs.	164,508
\$ 0.34	471,636	9.3 yrs.	0
\$ 1.01	141,007	9.1 yrs.	141,007
\$ 1.69	479,422	9.3 yrs.	169,208
\$ 2.39	305,000	9.8 yrs.	5,000
\$ 3.34	71,403	9.7 yrs.	0
\$ 0.07 - \$ 3.34	2,259,355	9.3 yrs.	592,531

In addition on December 31, 2004, the Company also had 277,731 warrants outstanding in connection with the Company's February 2004 Private Placement (see Note 5).

#### NOTE 5. PRIVATE PLACEMENTS OF COMMON AND PREFERRED SHARES

During February 2004, pursuant to a private placement memorandum, the Company sold 2,802,989 shares of common stock at a price of \$1.68 per share and received net proceeds of approximately \$4,379,155. In connection with the placement and as consideration for its services as placement agent, the Company paid cash fees of \$326,979 and issued warrants to purchase 277,731 shares of common stock at \$1.85 per share to a related party. These warrants were immediately exercisable and expire on February 15, 2009.

Immediately prior to the EMLR - Hana Biosciences merger in July 2004 (see Note 2), the Company raised gross proceeds of \$8 million through the sale of 2,395,210 shares of Series A Convertible Preferred Stock at \$3.34 per share. Following the Company's reincorporation in September

2004 (Note 2), each share of Series A Convertible Preferred Stock was convertible at the holder's election and without further consideration into 1.410068 common shares.

On January 18, 2005 the Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission. As a result of the effectiveness of the registration statement, all of the Series A Convertible Preferred Stock automatically converted into an aggregate of 3,377,409 common shares (see Note 13).

## NOTE 6. LICENSE AGREEMENTS

In December 2002, the Company entered into an exclusive worldwide royalty-bearing license agreement with Dana-Farber Cancer Institute and Ash Stevens, Inc. for its product PT-523. In consideration for the license, the Company paid to the licensors an initial license fee of \$100,000 and agreed to make additional payments totaling \$6 million upon the achievement of certain milestones, including a \$5 million payment upon approval by the FDA of a New Drug Application.

In February 2004, the Company entered into an exclusive worldwide, royalty-bearing license agreement with Yale University and The Research Foundation of State University of New York for its product IPdR. In consideration for the grant of the license, the Company paid Yale and SUNY an initial aggregate license fee of \$100,000 and issued 10 year options to purchase 100,000 shares of Hana's common stock. The Company is also required to make two additional license payments of \$250,000 each upon the completion of a Phase IIb clinical trial and upon New Drug Application approval by the FDA, respectively.

On October 26, 2004, the Company entered into a License Agreement with NovaDel Pharma, Inc. (NovaDel). Pursuant to the terms of the License Agreement, NovaDel granted to the Company a royalty-bearing exclusive right and license to develop and commercialize within the United States and Canada NovaDel's lingual spray version of ondansetron, the most widely prescribed anti-emetic for preventing chemotherapy-induced nausea and vomiting. The technology licensed to the Company under the license agreement currently covers one United States issued patent. In connection with the development of the licensed product, NovaDel has agreed to perform or cause to be performed certain development activities on behalf and at the expense of the Company.

The license agreement provides that (i) the Company will make royalty payments to NovaDel based on a percentage of "Net Sales" (as defined in the agreement); (ii) the Company is obligated to make various milestone payments in an aggregate amount of up to \$10 million.

As part of the agreement the Company has issued to NovaDel 73,121 shares of its common stock having a value of \$500,000 and the Company also purchased 400,000 shares of NovaDel's common stock for \$1,000,000 or \$2.50 per share. The fair value of the NovaDel shares equaled \$1.59 per share on the date of the license agreement and as a result, the Company has expensed the \$364,000 premium as a licensing fee in the accompanying 2004 statement of operations and recorded the balance of \$636,000 as an investment (see Note 11). Neither party may sell each other's shares for a 2-year period following the effective date of the license agreement.

The license agreement expires on the later of (i) the expiration date of the last to expire patent covered by the license (currently March 18, 2022) or (ii) 20 years from the effective date of the license agreement. The license agreement also provides that NovaDel may terminate the agreement upon notice prior to the expiration of its term in the event the Company becomes insolvent or defaults in its payment obligations, and either party may terminate the agreement after giving notice and an opportunity to cure in the event the other party commits a material breach.

## NOTE 7. NOTES PAYABLE

During 2003, the Company issued various notes payable to stockholders to fund the Company's operations. These notes had an interest rate of 5% and were originally due on January 15, 2005.

On August 18, 2004, the Company repaid all of its outstanding notes payable and accrued interest. The balance as of August 18, 2004 was repaid using cash of \$689,368 and the issuance of 63,326 shares of common stock having a fair value of \$150,000 (\$2.37 per share) for the repayment of the remaining balance of outstanding notes payable.

## NOTE 8. SHARES TO BE ISSUED

On September 23, 2004, the Board of Directors authorized the issuance of up to 60,000 shares to certain current and former employees and a director of the Company following the date the Company completed its reincorporation merger with EMLR, which was completed on September 30, 2004 (See Note 2). The final amount to be distributed subsequent to December 31, 2004 is 55,500 shares of common stock. Compensation expense of \$249,750 related to this issuance was recorded in the accompanying financial statements based on the fair market value of \$4.50 per share on the date of grant which was in the fourth quarter of 2004.

#### NOTE 9. INCOME TAXES

There was no current or deferred tax expense for the years ended December 31, 2003 and 2004 because of the Company's operating losses.

The components of deferred tax assets (there were no deferred tax liabilities) as of December 31, 2003 and 2004 are as follows:

	2003	2004
Deferred tax assets:		
Net operating loss carryforwards	\$285,000	\$2,508,000
Accrued compensation and accrued vacation	0	146,000
Stock-based compensation	0	409,000
Fixed assets and license agreements	9,000	368,000
	<u>294,000</u>	<u>3,431,000</u>
Less valuation allowance	(294,000 )	(3,431,000 )
Deferred tax assets, net	<u>\$—</u>	<u>\$—</u>

A valuation allowance is provided against deferred tax assets when it is more likely than not that some portion or all of those deferred tax assets will not be realized. Due to the uncertainties related to the Company's ability to realize benefits from its deferred tax assets in subsequent years, the Company recorded valuation allowances to fully offset its deferred tax assets. The net increases in the total valuation allowance for the years ended December 31, 2003 and 2004 were an increase of \$238,000 and \$3,137,000, respectively. The tax benefits expected based on the Company's pre-tax losses in 2003 and 2004 and using the federal statutory tax rate of 34% have been reduced to an actual benefit of zero due principally to the aforementioned increases in the valuation allowance.

At December 31, 2004, the Company had potentially utilizable federal and state net operating loss tax carryforwards of approximately \$5,861,000 and \$5,720,000, respectively. The net operating loss carryforwards expire in various amounts through 2023 for federal and state tax purposes.

#### NOTE 10. COMMITMENTS AND CONTINGENCIES

##### LEASE COMMITMENTS

In December 2004 the Company entered into an office lease that expires on December 31, 2005. The aggregate amount of lease payments over the remaining term amounted to approximately \$121,000 at December 31, 2004. Rent expense totaled approximately \$111,000 in 2004 and \$10,000 in 2003.



## EMPLOYMENT AGREEMENTS

The Company entered into a written three year employment agreement with its President and Chief Executive Officer dated November 1, 2003. The aggregate amount of compensation to be provided over the remaining term of the agreement amounted to approximately \$458,000 at December 31, 2004.

The Company entered into a written two year employment agreement with its Vice President of Business Development on January 25, 2004. The aggregate amount of compensation to be provided over the remaining term of the agreement amounted to approximately \$175,000 at December 31, 2004.

The Company entered into a written three year employment agreement with its Vice President and Chief Medical Officer on October 21, 2004. The aggregate amount of compensation to be provided over the remaining term of the agreement amounted to approximately \$425,000 at December 31, 2004.

The Company entered into a written three year employment agreement with its Vice President and Chief Financial Officer on November 15, 2004. The aggregate amount of compensation to be provided over the remaining term of the agreement amounted to approximately \$511,000 at December 31, 2004.

## NOTE 11. INVESTMENT IN EQUITY SECURITIES

As explained in Note 6, during October 2004, the Company acquired 400,000 shares of common stock from NovaDel for, effectively, \$636,000. The Company is restricted from selling the shares for two years. Accordingly, the Company is accounting for the shares using the cost method. If the shares owned by the Company had been unrestricted at December 31, 2004, they would have had a market value of \$656,000. Accordingly, the Company believes the carrying value of the shares approximated their fair value and no charge for impairment was required.

## NOTE 12. 401(K) SAVINGS PLAN

During 2004, the Company has adopted a 401(k) Plan (the "401(k) Plan") for the benefit of its employees. The Company is required to make matching contributions to the 401(k) Plan equal to 100% of the first 5% of wages deferred by each participating employee. During 2004, the Company incurred a total charge of approximately \$45,000 for employer matching contributions.

## NOTE 13. SUBSEQUENT EVENTS

On January 18, 2005 the Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission. The Company filed and requested effectiveness of the SB-2 resale registration statement to satisfy certain of its obligations in connection with its two most recent private placements in February and July 2004. The registration statement covers the resale of the common shares underlying the Company's Series A Convertible Preferred Stock issued in July 2004, among others. As a result of the effectiveness of the registration statement, all of the Series A Convertible Preferred Stock automatically converted into an aggregate of 3,377,409 common shares on January 18, 2005.

**7,340,317 Shares**

**Common Stock**

**Hana Biosciences, Inc.**

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PROSPECTUS

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April 29, 2005