G WILLI FOOD INTERNATIONAL LTD
Form 6-K
November 27, 2017

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

For the month of November 2017

G. Willi-Food International Ltd.
(Translation of registrant's name into English)

4 Nahal Harif St., Yavne, Israel 81106
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F £

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No S

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-
_____

Attached hereto and incorporated by reference herein is a press release, dated November 27, 2017, entitled "G. Willi-Food International reports improvements in major operational parameters in Q3 2017 compared to Q3 2016". This Form 6-K is hereby incorporated by reference in the Registration Statements on Form F-3 (File No. 333-11848 and 333-138200) of the Registrant.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

G. Willi-Food International Ltd.

By: /s/ Amir Kaplan
Name: Amir Kaplan
Title: Chief Financial Officer

Date: November 27, 2017

FOR IMMEDIATE RELEASE

G. WILLI-FOOD INTERNATIONAL REPORTS IMPROVEMENTS IN MAJOR OPERATIONAL PARAMETERS IN Q3 2017 COMPARED TO Q3 2016

Q3 2017 Net Profit up 83.4% from Q3 2016

YAVNE, Israel - November 27, 2017 - G. Willi-Food International Ltd. (NASDAQ: WILC) (the "Company" or "Willi-Food"), a global company that specializes in the development, marketing and international distribution of kosher foods, today announced its unaudited financial results for the third quarter ended September 30, 2017.

Willi-Food's operating divisions include Willi-Food, a distributor of a broad variety of kosher foods, and its wholly-owned Gold Frost, a designer, developer and distributor of branded kosher innovative dairy food products.

Third Quarter Fiscal 2017 Highlights (income statement highlights compared to same period last year)

- Sales increased 13.3% from third quarter of 2016 to NIS 80 million (US$ 22.7 million)
- Gross profit increased by 9.8% year-over-year to NIS 20.8 million (US$ 5.9 million).
- Operating profit of NIS 8.2 million (US$ 2.3 million), or 10.3% of sales, compared to operating profit of NIS 4.8 million (US$ 1.4 million) in the comparable quarter of 2016.
- Net profit was NIS 8.2 million (US$ 2.3 million), or 10.2% of sales, an increase of 83.4% versus the third quarter of 2016.
- Net cash from operating activities of NIS 31.0 million (US$ 8.8 million).
- Cash and securities balance of NIS 234.3 million (US$ 66.4 million) as of September 30, 2017.
- Earnings per share of NIS 0.62 (US$ 0.18).

Management Comment

Tim Cranko, CEO of Willi-Food, commented: "We are pleased to present the third quarter 2017 financial report which shows improvements in operations and in results. Sales increased 13.3% versus third quarter 2016, gross profit increased 9.8% and total operating expenses decreased by 11%, together leading to an increase in operating profit of 70.1% versus third quarter of 2016. A major area of focus during the quarter was inventory optimization. While this is still an area of focus, we are pleased to report that the level of inventory was reduced by 41.3% from NIS 70.9 million (US$ 20.1) at the end of second quarter of 2017 to NIS 41.6 million (US$11.8) at the end of the third quarter of 2017. During the third quarter, we began integrating a new senior management team which initiated the introduction of management systems, routines and procedures. These management changes and initiatives allow for organizational stability and provide a solid basis for enhanced future growth."

Third Quarter Fiscal 2017 Summary

Sales for the third quarter of 2017 increased by 13.3% to NIS 80.0 million (US$ 22.7 million) from NIS 70.6 million (US$ 20 million) recorded in the third quarter of 2016. The increase in sales was primarily due to a strike at the Ministry of Health in the third quarter of 2016 which limited release of goods from the port and caused a decrease of NIS 6 million in sales in the third quarter of 2016 offset by an increase in sales due to and various sales promotions in the third quarter of 2017.

Gross profit for the third quarter of 2017 increased by 9.8% to NIS 20.9 million (US$ 5.9 million) compared to NIS 19.0 million (US$ 5.4 million) recorded in the third quarter of 2016. Third quarter 2017 gross margin decreased by 3% to 26.1% compared to gross margin of 26.9% for the same period in 2016. The decrease in gross margin was primarily due to reductions in the prices of certain of our products as a result of an inventory with a short expire date that the Company had to sell with lower prices.

Willi-Food's operating profit for the third quarter of 2017 increased by 70.8% to NIS 8.2 million (US$ 2.3 million) compared to operating profit of NIS 4.8 million (US$ 1.4 million) in the third quarter of 2016. Selling expenses decreased by 12.7% from the comparable quarter of 2016 primarily due to a decrease in promotional expenses which was somewhat offset by an increase of inventory-storage expenses. Selling expenses as a percentage of sales were 11.6%, compared to 15% in the third quarter of 2016.

General and administrative expenses were NIS 3.3 million (US$ 0.9 million) in the third quarter of 2017, a decrease of 9% compared to NIS 3.7 million (US$ 1 million) in third quarter of 2016, mainly due to a decrease in senior management salary.

Willi-Food's income before taxes for the third quarter of 2017 was NIS 10.9 million (US$ 3.1 million) compared to income before taxes of NIS 5.5 million (US$ 1.5 million) recorded in the third quarter of 2016.

Willi-Food's net profit in the third quarter of 2017 was NIS 8.2 million (US$ 2.3 million), or NIS 0.62 (US$ 0.17) per share, compared to NIS 4.5 million (US$ 1.3 million), or NIS 0.34 (US$ 0.1) per share, recorded in the third quarter of 2016.

Willi-Food ended the third quarter of 2017 with NIS 234 million (US$ 66 million) in cash and securities. Net cash from operating activities for the third quarter of 2017 was NIS 31.0 million (US$ 8.7 million). Willi-Food's shareholders' equity at the end of September 2017 was NIS 404.7 million (US$ 114.7 million).

Nine months Fiscal 2017 Highlights (compared to same period last year)

- Sales increased 4.3% to NIS 239.7 million (US$ 67.9 million).
- Gross profit decreased 6.2% to NIS 57.5 million (US$ 16.2 million), or 24.0% of sales.
- Operating profit decreased 35.8% to NIS 13.2 million (US$ 3.7 million), or 5.5% of sales.
- Net income decreased 17.1% to NIS 14.0 million (US$ 3.9 million), or 5.9% of sales.
- Net cash used for operating activities of NIS 5.3 million (US$ 1.5 million)
- Earning per share of NIS 1.06 (US$ 0.3).

Nine Month Results

Willi-Food's sales for the nine month period ending September 30, 2017 increased by 4.3% to NIS 239.7 million (US$ 67.9 million) compared to sales of NIS 229.8 million (US$ 65 million) in nine months of 2016. The increase in sales was primarily due to a strike at the Ministry of Health in the third quarter of 2016 which limited release of goods from the port and caused a decrease of NIS 6 million in sales in the corresponding period last year offset by an increase in sales due to and various sales promotions in the third quarter of 2017.

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Gross profit for the period decreased by 6.2% to NIS 57.5 million (US$ 16.2 million) compared to gross profit of NIS 61.3 million (US$ 17.3 million) for nine months of 2016. Nine months of 2017 gross margin was 24.0% compared to a gross margin of 26.6% for the same period in 2016.

Operating profit for nine months of 2017 decreased by 35.8% to NIS 13.2 million (US$ 3.7 million) from NIS 20.6 million (US$ 5.8 million) reported in the comparable period of last year primarily due to the decrease of gross profit and increase of selling expenses. Nine months of 2017 income before taxes decreased by 20.1% to NIS 17.7 million (US$ 5.0 million) compared to NIS 22.1 million (US$ 6.3 million) recorded in the nine months of 2016. Net income for the nine months of 2017 decreased by 17.1% to NIS 14.0 million (US$ 3.9 million), or NIS 1.06 (US$ 0.30) per share, from NIS 16.9 million (US$ 4.8 million), or NIS 1.28 (US$ 0.34) per share, recorded in nine months of 2016.

Note regarding a notice of the end of Exclusive Distribution Agreement

On October 19, 2017 the Company's wholly owned subsidiary, Gold Frost Ltd. ("Goldfrost"), received a notice from its Danish producer of dairy products, Arla Foods amba ("Arla"), to end their Exclusive Distribution Agreement effective as of December 31, 2017.

As announced by the Company, the end of the Exclusive Distribution Agreement with Arla may have a significant negative impact on the Company's operating results although the Company believes that it will be able to enter into agreements in the near future with alternative suppliers for a portion of the products currently purchased from Arla.

Representatives of the Company's wholly owned subsidiary, Goldfrost, and representatives of Arla have met several times in recent weeks and have agreed that Goldfrost may place new orders for additional dairy products produced by Arla and to be sold by Goldfrost during the first half of 2018.
Goldfrost intends to continue its communications with Arla.

Note A: Convenience Translation to Dollars

The convenience translation of New Israeli Shekels (NIS) into U.S. dollars was made at the rate of exchange prevailing on September 30, 2017, U.S. $1.00 equals NIS 3.529. The translation was made solely for the convenience of the reader.

Note B: IFRS

The Company's consolidated financial results for the six-month period ended September 30, 2017 are presented in accordance with International Financial Reporting Standards ("IFRS").

ABOUT G. WILLI-FOOD INTERNATIONAL LTD.:

G. Willi-Food International Ltd. (http://www.willi-food.com) is an Israeli-based company specializing in high-quality, great-tasting kosher food products. Willi-Food is engaged directly and through its subsidiaries in the design, import, marketing and distribution of over 600 food products worldwide. As one of Israel's leading food importers, Willi-Food markets and sells its food products to over 1,500 customers in Israel and around the world including large retail and private supermarket chains, wholesalers and institutional consumers. The company's operating divisions include Willi-Food in Israel and Gold Frost, a wholly owned subsidiary who designs, develops and distributes branded kosher, dairy-food products.

FORWARD LOOKING STATEMENT

This press release contains forward-looking statements within the meaning of safe harbor provisions of the Private Securities Litigation Reform Act of 1995 relating to future events or our future performance, such as statements

regarding trends, demand for our products and expected sales, operating results, and earnings. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in those forward-looking statements. These risks and other factors include but are not limited to: monetary risks including changes in marketable securities or changes in currency exchange rates- especially the NIS/U.S. Dollar exchange rate, payment default by any of our major clients, the loss of one or more of our key personnel, changes in laws and regulations, including those relating to the food distribution industry, and inability to meet and maintain regulatory qualifications and approvals for our products, termination of arrangements with our suppliers, loss of one or more of our principal clients, increase or decrease in global purchase prices of food products, increasing levels of competition in Israel and other markets in which we do business, changes in economic conditions in Israel, including in particular economic conditions in the Company's core markets, our inability to accurately predict consumption of our products and changes in consumer preferences, our inability to protect our intellectual property rights, our inability to successfully integrate our recent acquisitions, insurance coverage not sufficient enough to cover losses of product liability claims and risks associated with product liability claims. We cannot guarantee future results, levels of activity, performance or achievements. The matters discussed in this press release also involve risks and uncertainties summarized under the heading "Risk Factors" in the Company's Annual Report on Form 20-F for the year ended December 31, 2016, filed with the Securities and Exchange Commission on April 27, 2017. These factors are updated from time to time through the filing of reports and registration statements with the Securities and Exchange Commission. We do not assume any obligation to update the forward-looking information contained in this press release.

{FINANCIAL TABLES TO FOLLOW}

G. WILLI-FOOD INTERNATIONAL LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30,		December 31	September 30,		December 31
	2017	2016	2016	2017	2016	2016
	NIS (in thousands)			US dollars (*)		
ASSETS						
Current assets						
Cash and cash equivalents	111,350	237,613	129,577	31,553	63,228	36,718
Financial assets carried at fair value through profit or loss	122,981	14,948	104,921	34,849	3,978	29,731
Trade receivables	95,993	83,379	80,227	27,201	22,187	22,734
Other receivables and prepaid expenses	2,621	5,263	4,795	743	1,400	1,358
Inventories	41,646	44,982	41,877	11,801	11,970	11,867
Current tax assets	6,308	3,351	5,443	1,787	892	1,542
Total current assets	380,899	389,536	366,840	107,934	103,655	103,950
Non-current assets						
Property, plant and equipment	78,315	77,116	77,204	22,192	20,520	21,877
Less -Accumulated depreciation	36,530	34,024	34,963	10,351	9,054	9,907
	41,785	43,092	42,241	11,841	11,466	11,970
Non current financial assets	-	7,900	-	-	2,102	-
Goodwill	36	36	36	10	10	10
Deferred taxes	1,619	2,313	2,354	459	617	667
Total non-current assets	43,440	53,341	44,631	12,310	14,195	12,647
	424,339	442,877	411,471	120,244	117,850	116,597
EQUITY AND LIABILITIES						
Current liabilities						
Trade payables	10,463	21,788	14,832	2,965	5,798	4,203
Employees Benefits	2,117	2,335	2,253	600	621	638
Other payables and accrued expenses	5,789	1,542	2,533	1,641	410	717
Total current liabilities	18,369	25,665	19,618	5,206	6,829	5,558
Non-current liabilities						
retirement benefit obligation	1,212	544	849	343	145	241
Total non-current liabilities	1,212	544	849	343	145	241
Shareholders' equity						
Share capital NIS 0.1 par value (authorized - 50,000,000 shares, issued and outstanding - 13,240,913 shares at March 31, 2017; and December 31, 2016)	1,424	1,424	1,424	404	379	404
Additional paid in capital	128,354	128,354	128,354	36,371	34,155	36,371
Capital fund	247	247	247	70	66	70

Remeasurement of the net liability in respect of defined benefit	(809)	(197)	(508)	(229)	(52)	(144)
Retained earnings	275,542	286,840	261,487	78,079	76,328	74,097
Equity attributable to owners of the Company	404,758	416,668	391,004	114,695	110,876	110,798
	424,339	442,877	411,471	120,244	117,850	116,597

(*) Convenience translation into U.S. dollars.

G. WILLI-FOOD INTERNATIONAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Nine months ended September 30,		Three months ended September 30,		Nine months ended September 30		
	2017	2016	2017	2016	2017	20	
	NIS				US dollars (*		
	In thousands (except per share and share data)						
Sales	239,771	229,849	80,041	70,621	67,943	61	
Cost of sales	182,270	168,524	59,166	51,616	51,649	44	
Gross profit	57,501	61,325	20,875	19,005	16,294	16	
Operating costs and expenses:							
Selling expenses	32,296	29,148	9,260	10,606	9,152	7,7	
General and administrative expenses	12,229	11,605	3,352				

time and cost necessary to seek third party manufacturers to manufacture our products for us;

time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;

time and cost necessary to respond to technological and market developments;

changes made or new developments in our existing collaborative, licensing and other commercial relationships; and

new collaborative, licensing and other commercial relationships that we may establish.

Commitments

We have several financial commitments, including those relating to our license agreement with the University of California.

Under our license agreement with the University of California, we are required to:

pay minimum annual royalties on February 28 of each year beginning in the year 2004 in the amounts set forth below, to be credited against earned royalties, for the life of the agreement;

Year	Minimum Annual Royalty Due
2004	$ 50,000
2005	$ 100,000
2006	$ 150,000
2007	$ 200,000
2008	$ 400,000
2009	$ 600,000
2010	$ 800,000
2011	$ 1,500,000
2012	$ 1,500,000
2013	$ 1,500,000

maintain an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market; and

pay the costs of patent prosecution and maintenance of the patents included in the agreement.

In addition, our license agreement with Antares, the licensor of our hormone products, requires us to make certain payments as development milestones are achieved and our license agreement with the University of California, requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve research and development milestones. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

enter into additional leases for new facilities and capital equipment;

enter into additional licenses and collaborative agreements; and

incur additional expenses associated with being a public company.

In addition to the commitments to the University of California, we also have minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 211,292	$ 151,578	$ 59,714	$	$
Commitments Under License Agreement with UCLA	6,800,000		150,000	$ 350,000	$ 6,300,000
Commitments Under License Agreement with Wake Forest	1,140,000		55,000	145,000	940,000
Total Contractual Cash Obligations	$ 8,151,292	$ 151,578	$ 264,714	$ 495,000	$ 7,240,000

The capital equipment expenditures of $86,735 during 2001 were principally for the acquisition of office furniture and computer equipment. We expect to spend approximately $25,000 to $50,000 in capital expenditures during the next 12 months.

Outlook

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash resources, we believe we should be able to maintain our current pace and level of expenditures through December 2002, although no assurance can be given that we will not need additional cash prior to such time. Unexpected increases in general and administrative expenses and research and development expenses may cause us to need additional financing prior to December 2002. If we do not sell any of the shares offered in this offering, we believe our existing cash will be sufficient to fund our operations through December 2002. If we are able to sell all of the shares offered in this offering, we believe that with the net proceeds of this offering and our existing cash, we will have sufficient working capital to meet our needs through December 2003. We have based these estimates, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. If we are unable to sell any shares offered in this offering, we will be required to seek alternative forms of equity or debt financing. Any equity financing may be dilutive to our existing shareholders, and involve the issuance of securities that may have rights, preferences or privileges senior to those possessed by our current stockholders. A debt financing, if available, may involve restrictive covenants on our business which could limit our operational and financial flexibility, and the amount of debt incurred could make us more vulnerable to economic downturns and limit our ability to compete. We cannot be certain that any financing will be available when needed or will be on terms

acceptable to us. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business. We are required under the terms of our license agreement with the University of California, however, to have available certain amounts of funds for research and development activities.

BUSINESS

General

We are a development stage biopharmaceutical company that is developing a pipeline of hormone replacement products to treat hormone deficiencies in both men and women. We also are engaged in the development of our proprietary calcium phosphate, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants, drug delivery systems and to purify the milk of transgenic animals.

To enhance the value of our current pharmaceutical portfolio, we are pursuing the following corporate growth strategies:

- accelerate the development of our hormone replacement products;
- continue to develop our nanoparticle-based platform technology, or CAP, and seek assistance in such development through corporate partner sub-licenses;
- license or otherwise acquire other drugs that will add value to our current product portfolio; and
- implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

Our primary focus is to build a pipeline of hormone replacement products for the treatment of human hormone deficiencies. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis.

Our proposed hormone replacement products, which we license on an exclusive basis from Antares Pharma Inc., are gel formulations

of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and a progestogen. The gels are designed to be absorbed quickly through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. Human clinical trials have begun on four of our proposed hormone replacement products, a necessary step in the process of obtaining United States Food and Drug Administration, or FDA, approval to market the products.

The following is a list of our hormone replacement gel products in development:

LibiGel a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.

Bio-T-Gel a transdermal testosterone gel in development for testosterone deficiency in men.

Bio-E-Gel a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.

Bio-E/P-Gel a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.

LibiGel-E/T a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

Our CAP technology, which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles," as immune system boosters, for drug delivery, to purify the milk of transgenic animals, among other uses. We have identified three potential initial applications for our CAP technology:

the creation of improved versions of current vaccines and of new vaccines by the "adjuvant" activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response;

the creation of inhaled and oral forms of drugs that currently must be given by injection (*e.g.*, insulin); and

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown by selectively isolating biologically active therapeutic proteins from the transgenic milk.

The following is a list of our CAP products in development:

Bio-Vant CAP adjuvant technology new proprietary CAP technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases.

Bio-Air advanced proprietary technology using CAP as a delivery system for inhalable versions of therapies that currently must be injected.

CAP-Oral an advanced delivery system using proprietary CAP technology for oral administration of therapies that currently must be injected.

CAP biotechnology production use of CAP technology in a new patented process for extracting therapeutic proteins from transgenic milk.

Our company, which was initially formed as a corporation organized under the laws of the Province of Ontario on August 29, 1996, was continued as a corporation under the laws of the State of Wyoming on December 19, 1996 and reincorporated in Delaware on June 26, 2001. Our company is the continuing corporation resulting from an amalgamation, or consolidation, of three companies our company, which was previously named "Ben-Abraham Technologies Inc.," Structured Biologicals Inc., a corporation organized under the laws of the Province of Ontario, and 923934 Ontario Inc., a corporation organized under the laws of the Province of Ontario and a wholly owned subsidiary of Structured Biologicals. The amalgamation was approved by our stockholders on November 27, 1996 and the articles of arrangement were filed and became effective as of December 6, 1996. In November 1999, our stockholders approved the change of our corporate name from Ben-Abraham Technologies Inc. to BioSante Pharmaceuticals, Inc. In June 2001, our stockholders approved the reincorporation of our company to Delaware.

On May 31, 2002, we effected a one-for-ten reverse split of our issued and outstanding shares of common stock and class C stock. All share and per share numbers in this prospectus have been adjusted to reflect the reverse stock split.

Business Strategy

Our goal is to develop and commercialize our hormone replacement products and CAP technology into a wide range of pharmaceutical products. Key elements of our strategy to obtain this goal are to:

Accelerate the development of our hormone replacement products. We are focused on building a pipeline of hormone replacement products for the treatment of human hormone deficiencies. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis. Human clinical trials have begun on four of our proposed hormone replacement products, a necessary step in the process of obtaining FDA approval to market the products.

Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses. We are seeking opportunities to enter into business collaborations, joint ventures or sub-licenses with companies that have businesses or technologies complementary to our CAP technology business, such as vaccine and drug delivery pharmaceutical companies and transgenic milk companies. We believe that this partnering

strategy will enable us to capitalize on our partners' strengths in product development, manufacturing and commercialization and thereby enable us to introduce into the market products incorporating our CAP technology sooner than which we otherwise would be able. In addition, we believe these collaborations would significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology.

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies. We intend to seek opportunities to enter into business collaborations or joint ventures with entities that have businesses or technology complementary to our business. We are particularly interested in entering into product co-development and co-marketing arrangements.

License or otherwise acquire other drugs that will add value to our current product portfolio. We intend to seek opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. In seeking these opportunities, we intend to target products that cover therapeutic areas treated by a limited number of physicians and

drugs that are in or require human clinical trials that involve a limited number of patients and not a significant amount of time and cost needed to complete them. We believe that targeting these products that are currently in or ready for human clinical trials would decrease the risks associated with product development and would likely shorten the time before we can introduce the products into the market. In addition to late-stage development products, we intend to seek opportunities to in-license or otherwise acquire products that (1) have FDA approval, (2) have been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience, and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have a full portfolio in development.

Description of Our Proposed Hormone Replacement Products

We are focused on building a pipeline of hormone replacement products to treat hormone deficiencies in men and women. Our proposed hormone replacement products are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), a combination of estradiol and testosterone and a combination of estradiol and a progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

The following is a list our hormone replacement gel products in development:

LibiGel a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.

Bio-T-Gel a transdermal testosterone gel in development for testosterone deficiency in men.

Bio-E-Gel a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.

Bio-E/P-Gel a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.

LibiGel-E/T a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone may also experience loss of body hair, reduced

muscle mass, osteoporosis and bone fractures due to osteoporosis. Approximately five million men in the United States, primarily in the over age 40 male population group, have lower than normal levels of testosterone. Testosterone replacement therapy has been shown to restore levels of testosterone with minimal side effects.

Testosterone often is delivered through injections or dermal, or skin, patches. Delivery of testosterone through dermal patches was developed primarily to promote the therapeutic effects of testosterone replacement therapy without the often painful side effects associated with testosterone injections. Dermal patches, however, have been associated with skin irritation. Our testosterone formulated gel product for men, Bio-T-Gel, is designed to deliver the required amount of testosterone without the pain of injections and the skin irritation and discomfort associated with dermal patches. We are aware of one gel testosterone product for men currently on the market in the United States and several in development.

Estrogen deficiency in women can result in hot flashes and flushes, vaginal atrophy, decreased libido and osteoporosis. Hormone replacement in women decreases the chance that women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately twenty million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone replacement therapy.

Estrogen is most commonly given orally in pill or tablet form. There are several potential side effects, however, with the use of oral estrogen, including insufficient absorption by the circulatory system, gallstones and blood clots. Although dermal patches have been shown to avoid some of these problems, delivery of estrogen through dermal patches, like testosterone patches, can result in skin irritation. Our estrogen formulated gel product, Bio-E-Gel, is designed to deliver estrogen without the skin irritation associated with, and the physical presence of, dermal patches.

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product. Women whose uterus is intact often use a combined hormone replacement therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial cancer and endometrial hyperplasia associated with estrogen therapy in these women. In July 2002, the National Institutes of Health announced that it was discontinuing the estrogen-progestin oral tablet combination arm of the Women's Health Initiative study because Prempro, the combination oral HRT product used in the study, caused an increase in the risk of invasive breast cancer after an average of 5.2 years on therapy. Both the estrogen and progestin components of Prempro are different chemical entities than those used in our proposed gel formulated Bio-E/P-Gel,

and the means of delivery into the system are significantly different. Prempro is an oral tablet formulation consisting of conjugated equine estrogen and medroxyprogesterone acetate as active ingredients. Our proposed Bio-E/P-Gel is a gel formulated delivery system containing estradiol, which is identical to the estrogen produced naturally by a woman's ovaries, and progestin, different than the progestin in Prempro. The Women's Health Initiative study results do not necessarily apply to estrogen and progestin administered through the transdermal route and to different hormones which may provide a different risk-benefit profile. In addition, the intended use for our proposed gel-formulated HRT products is no more than two years.

We are also developing a testosterone formulated gel product for women, LibiGel. Though generally characterized as a male hormone, testosterone also is present in women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone replacement therapy can boost sexual desire and pleasure, increase bone density, raise energy levels and improve mood. Similarly, we are developing a combination gel product of testosterone and estradiol for women, LibiGel-E/T, for low libido or sex drive.

We believe our proposed hormone replacement products have a number of benefits, including the following:

- our transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus hormone patches;
- our transdermal gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;
- adding progestogen to estrogen may reduce the potential risks of endometrial cancer and endometrial hyperplasia of estrogen therapy alone when the uterus is intact;
- our transdermal gels have been shown to be absorbed evenly, thus allowing clinical hormone levels to reach the systemic circulation;
- hormone replacement therapy using gels may allow for better dose adjustment than either patches or oral pills or capsules; and
- clinical trials involving the hormone products are expected to be relatively small requiring fewer patients than most drug development projects, which will keep our costs, time and risks

associated with the FDA approval process down.

Human clinical trials have begun on four of our proposed hormone replacement products, which are required to obtain FDA approval to market the products.

We license our proposed hormone replacement products on an exclusive basis from Antares Pharma, Inc. under a license agreement we entered into in June 2000. Under the terms of our license agreement with Antares (which we have amended several times since June 2000), we acquired exclusive development and marketing rights, with the right to grant sub-licenses (1) to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, New Zealand, China, Indonesia and South Africa, (2) for the combination estradiol and progestogen product in the U.S. and Canada, and (3) for a transdermal hormone replacement gel containing a combination of estradiol and testosterone in the U.S., Canada, Mexico, Israel, Australia, New Zealand, Malaysia, China, Indonesia and South Africa.

In September 2000, we sublicensed the marketing rights for our female proposed hormone replacement products to Paladin Labs Inc. in Canada. In August 2001, we sublicensed our proposed estrogen/progestogen combination transdermal hormone replacement gel product to Solvay Pharmaceuticals, B.V. for development and sale in the U.S. and Canada.

On August 7, 2001, we entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the proposed estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay paid us an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin) and has agreed to make future milestone payments and pay escalating sales-based royalties. Solvay is responsible for all costs of development and marketing of the proposed estrogen/progestogen combination transdermal hormone replacement gel product. We have retained co-promotion rights to the product and will be compensated for sales we generate over and above those attributable to Solvay's marketing efforts.

In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by BioSante, regulatory milestones, maintenance payments and royalty payments by BioSante if the product gets approved and subsequently marketed.

Description of Our CAP Technology and Proposed CAP Technology Products

We believe our CAP technology will serve as an effective vehicle for delivering drugs and vaccines and enhancing the effects of

vaccines. The key component, calcium phosphate, or CAP, is on the FDA's GRAS (Generally Regarded as Safe) list. Our nanoparticles have successfully passed the first stage of toxicity studies for administration orally, into muscles, under the skin, and into the lungs by inhalation.

The following is a list of our CAP products in development:

Bio-Vant CAP adjuvant technology new proprietary CAP technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases.

Bio-Air advanced proprietary technology using CAP as a delivery system for inhalable versions of therapies that currently must be injected.

CAP-Oral an advanced delivery system using proprietary CAP technology for oral administration of therapies that currently must be injected.

CAP biotechnology production use of CAP technology in a new patented process for extracting therapeutic proteins from transgenic milk.

Research and development involving our CAP technology originated in a project set up under an agreement dated April 6, 1989 between the University of California and our predecessor company, Structured Biologicals, relating to viral protein surface absorption studies. The discovery research was funded by Structured Biologicals at UCLA School of Medicine and was based, in essence, on the use of extremely small, solid, uniform particles as components that could increase the stability of drugs and act as systems to deliver drugs into the body.

These ultra fine particles are made from inert, biologically acceptable materials, such as ceramics, pure crystalline carbon or biodegradable calcium phosphate. The size of the particles is in the nanometer range. A nanometer is one millionth of a millimeter and typically particles measure approximately 1,000 nanometers (nm). For comparison, a polio virus particle is about 27 nm in diameter, a herpes virus particle has a central core measuring 100 nm in diameter, contained in an envelope measuring 150-200 nm, while a tuberculosis bacterium is rod-shaped, about 1,200 nm long by 300 nm across. Because the size of these particles is measured in nanometers, we use the term "nanoparticles" to describe them.

We use the nanoparticles as the basis of a delivery system by applying a layer of a "bonding" coating of cellobiose or another carbohydrate derivative. The critical property of these coated nanoparticles is that biologically active molecules, proteins, peptides or pharmacological agents, for example, vaccine components like bacterial or viral antigens or proteins like insulin, attached to them retain their activity and can be protected from natural alterations to

their molecular structure by adverse environmental conditions. It has been shown in studies conducted by us that when these combinations are injected into animals, the attachment can enhance the biological activity as compared to injection of the molecule alone.

A major immune response that is triggered by these combination particles is the creation of antibody molecules, which can then specifically counteract an invading virus or bacterium. Similarly, a drug will produce an effect on an organ system only if it can attach to specific receptors on the surface of target cells (*e.g.*, tumor cells). The stabilizing and slow release capabilities of a drug carrier and delivery system based on this discovery can lead to significant advances towards finding more effective and less toxic or harmful molecules to seek out and attach to such receptors.

We believe our CAP technology has a number of benefits, including the following:

- it is biodegradable (capable of being decomposed by natural biological processes) and non-toxic and therefore potentially safe to use and introduce into the human body;
- it is fast, easy and inexpensive to manufacture, which will keep our costs down and potentially improve our profit margins;
- the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays, inhalation or orally, instead of using often painful and inconvenient injections; and
- it has excellent "loading" capacity the amount of molecules that can bond with the nanoparticles thereby potentially decreasing the dose needed to be taken by patients while enhancing the release capabilities.

Research in these areas has resulted in the issuance of a number of patents that we license from the University of California.

We have completed a Phase I human clinical trial of CAP as a vaccine adjuvant and delivery system, a necessary step in the process of obtaining FDA approval to market the product. The Phase I trial was a double blind, placebo controlled trial, in 18 subjects to determine the safety of CAP as a vaccine adjuvant. The trial results showed that there was no apparent difference in side-effect profile between CAP and placebo.

We plan to develop commercial applications of our CAP technology and any proprietary technology developed as a result of

our ongoing research and development efforts. Initially, we plan to pursue the development of (1) vaccine adjuvants, (2) drug delivery systems, including a method of delivering proteins (*e.g.*, insulin) through inhalation, orally and subcutaneous routes of administration, and (3) the purification of the milk of transgenic animals. Our pre-clinical research team in our laboratory in Smyrna, Georgia is currently pursuing the development of our CAP technology.

Vaccine adjuvants. We believe that our CAP nanoparticles may offer a means of preparing new improved formulations of current vaccines that are equal or better in their safety and immunogenicity, that is, in their capacity to elicit an immune response, compared to alum-formulated and non-adjuvanted vaccines but may be injected in lower concentrations and less often which could result in certain benefits, including cost savings and improved patient compliance. Also, we believe that CAP will allow for creation of safe and effective vaccines for diseases and conditions for which no vaccines currently exist.

We intend to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in vaccine development, co-development and co-marketing arrangements. We believe these collaborations may enable us to accelerate the development of potential improved vaccines. These arrangements also could include out-licenses of our CAP technology to vaccine companies and others for further development and marketing.

Our nanoparticles when combined with vaccine antigens have been shown in animal studies conducted by us and others to possess an ability to elicit a higher immune response than non-adjuvanted vaccines and an immune response of the same magnitude as alum-formulated vaccines but up to 100 times lower concentrations. These preclinical studies also have shown that our CAP nanoparticles also may sustain higher antibody levels over a longer time period than both alum-formulated vaccines and non-adjuvanted vaccines. Because our CAP nanoparticles are made of calcium phosphate, which has a chemical nature similar to normal bone material and therefore is natural to the human body, as opposed to aluminum hydroxide, or alum, which is not natural to the human body, we believe that our nanoparticles may be safer to use than alum. In our animal studies,

we observed no material adverse reactions when our CAP nanoparticles were administered at effective levels.

We filed an investigational new drug, or IND, application with the FDA in July 2000 to commence a Phase I human clinical trial. We completed our Phase I human clinical trial in October 2000. As discussed in more detail under the heading "Government Regulation," the purpose of a Phase I trial is to evaluate the metabolism and safety of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. The Phase I trial of our CAP specifically looked at safety parameters, including local irritation and blood chemistry changes. The trial was completed and there was no apparent difference in the side effects profile between CAP and

placebo.

In addition to continuing our own research and development in this area, we intend to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in co-development and co-marketing arrangements with respect to our CAP nanoparticles for use as a vaccine adjuvant. These arrangements also could include out-licenses of our CAP technology to vaccine companies and others for further development in their on-going vaccine development.

Our outlicensing activities with respect to our adjuvant, which we call Bio-Vant, for use in other companies' vaccines have to date included meeting with target companies and, in some cases, agreeing that the target company will test our adjuvant in their animal models. Thereafter, the target company may send to us its vaccine antigen or DNA which we will then formulate with our nanoparticles and return for use in the target company's animal models. Once this is completed, if the results are positive, we would negotiate an out-license agreement with the target company.

In November 1999, we announced that we formed a collaborative research alliance with Antares Pharma, Inc. to evaluate the efficacy of combining our nanoparticle drug delivery and adjuvant or immune system boosters with Antares' needle-free pressure injection. This research alliance evaluated the ability of the combined systems to deliver DNA vaccines as part of a DNA vaccine program at a major U.S. university. In August 2000, we announced initial preclinical results from our collaboration with Antares. The initial tests demonstrated that Antares' needle-free pressure assisted injections containing our CAP technology produced better cellular immune responses in the injected animals than the injections without our CAP technology. No further work related to our CAP technology with Antares is currently planned.

In June 2000, we announced an option license agreement with ID Biomedical Corporation to use CAP as an adjuvant in a second-generation vaccine against group-A streptococcus ("GAS"). GAS is considered a worldwide public health threat causing strep-throat, skin infections, rheumatic fever, invasive fasciitis (flesh eating disease), toxic shock syndrome and other diseases. We believe ID Biomedical has decided to proceed without the use of CAP in their GAS vaccine.

We announced in August 2000, a non-exclusive option license agreement with Antex Biologics, Inc. to conduct preclinical tests of CAP in vaccines against *Chlamydia pneumoniae* and *H. pylori*. This collaboration is ongoing.

In October 2001, we announced a non-exclusive license agreement with Corixa Corporation to use our Bio-Vant vaccine adjuvant in potential vaccines to be development by Corixa. This is the first license agreement signed by BioSante for the development of CAP as a vaccine adjuvant. Under the license agreement, Corixa has agreed to pay us milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using Bio-Vant and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-Vant, we will share in milestone payments and royalties received by Corixa. The license agreement covers access to Bio-Vant for a variety of cancer, infectious and auto immune disease vaccines.

Drug delivery systems. The third field of use in which we are exploring applying our CAP technology involves creating novel and improved forms of delivery of drugs, including proteins (*e.g.*, insulin). The attachment of drugs to CAP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We believe we may have successfully created a formulation for the inhaled delivery of insulin, which we call Bio-Air. We are in the process of contacting and meeting the insulin manufacturers and companies with devices for inhalation of drugs to pursue collaborations for this development. Furthermore, we have shown pre-clinical efficacy in the oral delivery of insulin in diabetic mouse models. In the oral insulin mouse models, our product, which we call CAP-Oral, has shown an 80% reduction of glucose levels for 12 hours versus 20-30% glucose reduction for five hours for free insulin. Our research and development efforts in this area are ongoing.

Transgenic Milk Purification. The fourth field of use in which we are exploring applying our CAP technology is in the purification of the milk of transgenic animals in which protein drugs are grown. This is achieved by selectively isolating biologically active therapeutic proteins from the transgenic milk. This method uses our CAP technology to recover greater than 90% of drug protein from the milk in a way that may require less downstream processing and may produce higher overall yields at lower cost than currently used methods. Our method dissolves casein clusters, thereby freeing the drug proteins, and then reforms the casein clusters using CAP as the core. Caseins are then removed from the milk, leaving high concentrations of the drug protein in the remaining crystal clear whey fraction.

Sales and Marketing

We currently have very limited sales and marketing personnel to sell on a commercial basis any of our proposed products. If and when we are ready to commercially launch a product, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner to assist us with this function.

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately $1,632,000 for the six month period ended June 30, 2002, $2,142,000 in the year ended 2001 and $1,888,000 in the year ended 2000 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues from the sale of our products, these research and development costs must be financed by us. We estimate that we are currently spending approximately $300,000 to $400,000 per month on research and development activities. These expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending

upon the resources available and our development schedule. Results of preclinical studies, clinical trials, regulatory decisions and competitive developments may significantly influence the amount of our research and development expenditures. In addition, we expect that our spending on product development will increase if we are successful at in-licensing or otherwise acquiring other late-stage development products.

Manufacturing

We currently do not have any facilities suitable for manufacturing on a commercial scale basis any of our proposed products nor do we have any experience in volume manufacturing. We will either find our own manufacturing facilities, hire additional personnel with manufacturing experience and comply with the extensive Good Manufacturing Practices, or GMP, regulations of the FDA and other regulations applicable to such a facility or we will more likely rely upon third-party manufacturers to manufacture our proposed products in accordance with these regulations.

In September 1999, we entered into an arrangement with the University of Iowa to manufacture our CAP nanoparticles for use in our Phase I human clinical trial. Under the arrangement, the University of Iowa manufactured both a trial batch of our CAP nanoparticles and a clinical batch which was used in the clinical trial.

Currently, our gel hormone products are manufactured through an exclusive agreement with Antares Pharma, Inc.

Patents, Licenses and Proprietary Rights

Our success depends and will continue to depend in part upon our ability to maintain our exclusive licenses, to maintain patent protection for our products and processes, to preserve our proprietary information and trade secrets and to operate without infringing the proprietary rights of third parties. Our policy is to attempt to protect our technology by, among other things, filing patent applications or obtaining license rights for technology that we consider important to the development of our business.

Antares Pharma, Inc. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares has granted us an exclusive license to four proposed hormone replacement products for the treatment of testosterone deficiency in men and women and estrogen deficiency in women, including rights to sublicense the hormone replacement technology, in order to develop and market the hormone replacement technology in certain territories. Antares has an issued patent for these technologies in the United States and has filed patent applications for this licensed technology in several foreign jurisdictions, including Argentina, Australia, Canada, Europe, Italy, Japan, Korea, New Zealand, South Africa, and Taiwan.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of the four previously licensed hormone products, namely the

estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the single entity estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for a transdermal hormone replacement gel combination of testosterone and estradiol. In August 2002, BioSante and Antares further amended the license agreement to clarify interpretations of the license agreement, including products covered by the license agreement, and to terminate the Supply Agreement with Antares.

The license agreement with Antares required us to pay a $1,000,000 up-front license fee to Antares, which we paid in June 2000. Also pursuant to the terms of the Antares license agreement, we expect to:

- pay royalties to Antares based on a percentage of the net sales of any products we sell incorporating the licensed technology;
- accelerate the human clinical development of the hormone product portfolio, including:
  - testing proposed products;
  - conducting clinical trials;
  - obtaining government approvals;
  - introducing products incorporating the licensed technology into the market; and
- enter into sub-license arrangements or agreements with other entities regarding development and commercialization of the technology covered by the license.

University of California. In June 1997, we entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted us an exclusive license to nine United States patents owned by the University, including rights to sublicense such patents, in fields of use initially pertaining to: (1) vaccine adjuvants; (2) vaccine constructs or combinations for use in immunization against herpes virus; (3) drug delivery systems; and (4) red blood cell surrogates. The University of California has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan.

The license agreement with the University of California requires us to undertake various obligations, including:

- payment of royalties to the University based on a percentage of the net sales of any products we sell incorporating the licensed technology;
- payment of minimum annual royalties on February 28 of each year beginning in the year 2004 to be credited against earned royalties, for the life of the agreement;
- maintaining an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market;
- payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which amounted to $11,358 in fiscal 2001;
- meeting performance milestones relating to:
  - hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;
  - testing proposed products;
  - conducting clinical trials;
  - obtaining government approvals;
  - introducing products incorporating the licensed technology into the market; and
- entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.

The license agreement further provides that we have the right to abandon any project in any field of use without abandoning our license to pursue other projects in that or other fields of use covered by the agreement. In May 1999, we notified the University that we

would not pursue the red blood cell surrogate use because we did not believe it will be proven an effective use of CAP. In October 1999, we signed an amendment to our license agreement with the University, which removed the red-blood cell surrogate use from the agreement. In addition, under the terms of the amendment, the University agreed to make other changes we suggested to the license agreement, including delaying minimum royalty payments until 2004 and limiting the University's rights to terminate the agreement in cases where we do not perform under the agreement. If we violate or fail to perform any term or covenant of the license agreement and fail to cure this default within 60 days after written notice from the University, the University may terminate some projects included in the agreement. In May 2001, we signed a second amendment to our license agreement with the University to amend certain provisions of the license agreement for sublicensing arrangements with third parties.

Patents and patent applications. We own one United States patent and no foreign patents. In June 1999, we filed a patent for our advanced method of selectively isolating biologically active therapeutic proteins from transgenic milk. This patent was issued in February 2001. In February 2000, we filed a patent application with the U.S. Patent and Trademark Office relating to our development

work with vaccine adjuvants, conventional DNA and RNA vaccines and drug delivery, including aerosol delivery into the lungs. In addition, there are two other patent applications pending for products in development.

Trademarks and trademark applications. We have filed trademark applications in the U. S. for the mark BIOSANTE for vaccines and vaccine adjuvants and for our proposed hormone replacement products. Both applications have been allowed for registration and will register upon submission of proof of use. We have also filed U.S. trademark applications and received Notices of Allowance for the marks BIOVANT, BIOAIR, NANOVANT and LIBIGEL. Two other U. S. trademark applications are pending for BIO-E-GEL and BIO-T-GEL for products in development. The BIOSANTE mark is registered in the European Union and Israel, and BIO-E-GEL and BIO-T-GEL are registered in Mexico. In addition, there are 17 other applications pending in the European Union and other countries for marks including the BIOSANTE mark. We do not have any other registered trademarks.

Confidentiality and assignment of inventions agreements. We require our employees, consultants and advisors having access to our confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with us. These agreements generally provide that all confidential information we develop or make known to the individual during the course of the individual's employment or consulting relationship with us must be kept confidential by the individual and not disclosed to any third parties. We also require all of our employees and consultants who perform research and development for us to execute agreements that generally provide that all inventions conceived by these individuals will be our property.

Competition

There is intense competition in the biopharmaceutical industry, including in the hormone replacement therapy market, the market for prevention and/or treatment of the same infectious diseases we target and in the acquisition of products in the late-stage development phase or already on the market. Potential competitors in the United States are numerous and include major pharmaceutical and specialized biotechnology companies, universities and other institutions. In general, competition in the pharmaceutical industry can be divided into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions.

All of our competitors in categories (1) and (2) and some of our competitors in category (3) have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than we do, as well as substantially greater experience than us in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products.

A significant amount of research in the field is being carried out at academic and government institutions. These institutions are becoming increasingly aware of the commercial value of their findings and are becoming more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

We expect our products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market.

We are aware of certain programs and products under development by others which may compete with our proposed hormone replacement products and products we may develop that incorporate our

CAP technology. Several competing companies, including Wyeth-Ayerst Pharmaceuticals, Novartis AG, Solvay Pharmaceuticals, Inc., Noven Pharmaceuticals, Inc. and Berlex Laboratories, Inc., dominate the international hormone replacement industry. The international vaccine industry is dominated by three companies: GlaxoSmithKline, Aventis (through its subsidiaries, including Institut Merieux International, Pasteur Merieux Serums et Vaccins, Connaught Laboratories Limited and Connaught Laboratories, Inc.) and Merck & Co., Inc.

There are several firms currently marketing or developing transdermal hormone replacement products. They include The Procter & Gamble Company, Noven Pharmaceuticals, Inc., Novavax, Inc., Cellegy Pharmaceuticals, Inc., Auxilium A2, Inc., Watson Pharmaceuticals Inc. and Solvay Pharmaceuticals, Inc.

With regard to our CAP technology, the larger, better known pharmaceutical companies have generally focused on a traditional synthetic drug approach, although some have substantial expertise in biotechnology. During the last decade, however, significant research activity in the biotechnology industry has been completed by smaller research and development companies, like us, formed to pursue new technologies. Competitive or comparable companies to us include Corixa Corporation, generally regarded as a leader in vaccine adjuvant development, ID Biomedical Corporation and Antex Biologicals Inc., which both develop sub-unit vaccines from mycobacteria and other organisms.

Governmental Regulation

Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA regulations in the United States and by comparable regulations in foreign countries. Any products developed by us will require FDA approvals in the United States and comparable approvals in foreign markets before they can be marketed. The process of seeking and obtaining FDA approval for a previously unapproved new human pharmaceutical product generally requires a number of years and involves the expenditure of substantial resources.

Following drug discovery, the steps required before a drug product may be marketed in the United States include:

- preclinical laboratory and animal tests;
- the submission to the FDA of an investigational new drug application, commonly known as an IND application;
- clinical and other studies to assess safety and parameters of use;
- adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug product;
- the submission to the FDA of a new drug application, commonly known as an NDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the product.

Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a proposed product's uses and physiological effects and harmful effects, if any, and to

identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information.

The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

Phase II trials are designed to evaluate the effectiveness of the product in the treatment of a given disease and involve people with the disease under study. These trials often are well controlled, closely monitored studies involving a relatively small number of subjects, usually no more than several hundred. The optimal routes, dosages and schedules of administration are determined in these studies. If Phase II trials are completed successfully, Phase III trials are often commenced, although Phase III trials are not always required.

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials usually include from several hundred to several thousand subjects.

A clinical trial may combine the elements of more than one Phase and typically two or more Phase III studies are required. A company's designation of a clinical trial as being of a particular Phase is not necessarily indicative that this trial will be sufficient to satisfy the FDA requirements of that Phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one Phase notwithstanding the designation of the trial as being of a particular Phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to

complete Phase I, II and III studies with respect to a given product.

Upon the successful completion of clinical testing, an NDA is submitted to the FDA for approval. This application requires detailed data on the results of preclinical testing, clinical testing and the composition of the product, specimen labeling to be used with the drug, information on manufacturing methods and samples of the product. The FDA typically takes from six to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further, there is no assurance that the FDA will ultimately approve an NDA. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with current "good manufacturing practice" regulations, commonly referred to as "GMP" regulations, which govern the production of pharmaceutical products. We currently do not have manufacturing capability. In the event we undertake any manufacturing activities or contract with a third-party manufacturer to perform our manufacturing activities, we intend to establish a quality control and quality assurance program to ensure that our products are manufactured in accordance with the GMP regulations and any other applicable regulations.

Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, 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 European countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. We intend to seek and utilize foreign partners to apply for foreign approvals of our products.

Employees

We had twelve full-time employees as of June 30, 2002, including nine in research and development and three in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We believe we have an excellent relationship with our employees.

Properties

Our principal executive office is located in Lincolnshire, Illinois. In September 2001, we entered into a new lease agreement for approximately 4,034 square feet of office space for approximately

$6,200 per month, which lease expires in December 2003. Our CAP research and development operations are located in Smyrna, Georgia where we lease approximately 11,840 square feet of laboratory space for approximately $5,400 per month. This lease expires in October 2003. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

Legal Proceedings

We are not a party to any material, threatened or pending legal proceedings.

MANAGEMENT

Executive Officers, Directors and Key Employees

Set forth below is information concerning our executive officers, directors and key employees, including their age, as of August 13, 2002:

Name	Age	Title
Stephen M. Simes	50	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	42	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	39	Vice President, Clinical Development
Steven J. Bell, Ph.D.	42	Vice President, Research and Pre-Clinical Development
Louis W. Sullivan, M.D. (1)(2)(3)	68	Chairman of the Board
Victor Morgenstern (2)	59	Director
Fred Holubow (3)	63	Director
Ross Mangano (1)	56	Director
Edward C. Rosenow III, M.D. (3)	67	Director
Angela Ho (2)	49	Director
Peter Kjaer (1)	41	Director

(1) Member of the audit and finance committee

(2) Member of the compensation committee

(3) Member of the scientific review committee

Stephen M. Simes has served as our Vice Chairman, President and a director of our company since January 1998 and Chief Executive Officer since March 1998. From October 1994 to January 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Bio-Technology General Corp., and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Bio-Technology General Corp. Mr. Simes' career in the pharmaceutical industry started in 1974 with G.D. Searle & Co.

Phillip B. Donenberg, CPA has served as our Chief Financial Officer, Treasurer and Secretary since July 1998. Before joining our company, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. from January 1995 to July 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc., Molecular Geriatrics Corporation and Xtramedics, Inc.

Leah M. Lehman, Ph.D. has served as our Vice President, Clinical Development since January 2001. Prior to joining our company, Dr. Lehman was Director of Clinical Research with Scientific Research Development Corp. from April 1995 to December 2000. From 1993 to 1995, Dr. Lehman was a clinical statistician at Abbott Laboratories.

Steven J. Bell, Ph.D. has served as our Vice President, Research and Pre-Clinical Development since October 2000 and served as a Director of Research and Development of BioSante from July 1997 to October 2000. Prior to joining our company, Dr. Bell held various positions with Boehringer Mannheim, Hoffman-LaRoche, The Upjohn Company and Boehringer Ingelheim.

The Honorable Louis W. Sullivan, M.D. has been our Chairman of the Board of Directors since March 1998 and has been a director of our company since its formation. Dr. Sullivan served as Secretary of Health and Human Services in the cabinet of President George Bush from 1989 to 1993. Since retiring from the Bush Administration, Dr. Sullivan is currently President Emeritus of the Morehouse School of Medicine in Atlanta, Georgia. He had previously served as President and Dean of the School from 1981 to 1985 and President from 1985 to 1989 and from 1993 to 2002. Since 1993, Dr. Sullivan has served and continues to serve on the Boards of several large U.S. corporations, including 3M Corp., Bristol-Myers Squibb Company, Cigna Corporation, Georgia Pacific Corp. and Household International Inc.

Victor Morgenstern was elected a director of our company in July 1999. Mr. Morgenstern has more than 32 years of investment experience and is the Chairman of the Board of Trustees of The Oakmark Funds, an open-end registered investment company and

serves as managing director of Resolute Partners L.P. He is a trustee of the Illinois Institute of Technology.

Fred Holubow was elected a director of our company in July 1999. Mr. Holubow has been a Vice President of Pegasus Associates since he founded Pegasus in 1982. Pegasus Associates is currently an operating division of William Harris Investors, a registered investment advisory firm. He specializes in analyzing and investing in pharmaceutical and biotechnology companies. Mr. Holubow has served on the Boards for Bio-Technology General Corp., ThermoRetec Corporation, Gynex Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc. and Gynex Pharmaceuticals, Inc.

Ross Mangano was elected a director of our company in July 1999. Mr. Mangano has been the President and a director of Oliver Estate, Inc., a management company specializing in investments in public and private companies since 1971. He is the Chairman of Cerprobe Corporation, and serves as a director for Blue Chip Casino, Inc., Orchard Software Corporation, and U.S. RealTel Inc.

Edward C. Rosenow, III, M.D. has been a director of our company since November 1997. Dr. Rosenow is a Master Fellow of the American College of Physicians as well as Master Fellow of the American College of Chest Physicians. Dr. Rosenow was the Arthur M. and Gladys D. Gray Professor of Medicine at the Mayo Clinic from 1988 until his recent retirement. Beginning with his residency in 1960, Dr. Rosenow has worked at the Mayo Clinic in many professional capacities including as a Consultant in Internal Medicine (Thoracic Diseases) from 1966 to 1996, an Assistant Professor, Associate Professor and Professor of Medicine at the Mayo Clinic Medical School, President of the Mayo Clinic Staff in 1986, and Chair of the Division of Pulmonary and Critical Care Medicine from 1987 to 1994. Dr. Rosenow has also served as a consultant to NASA, space station FREEDOM at the Johnson Space Center in Houston, Texas from 1989 to 1990 and as the President of the American College of Chest Physicians from 1989 to 1990. In 1998, he received the Mayo Distinguished Alumnus Award.

Angela Ho has been a director of our company since June 1998. Ms. Ho was elected to our Board of Directors as a representative of certain major investors in Hong Kong. Ms. Ho has been the Vice Chairman and Chief Managing Officer of Jet-Asia Ltd., a Hong Kong-based aircraft and management company, since April 1996. From June 1996 to June 1998, Ms. Ho was the President of Ho Galleries Ltd., a New York art gallery.

Peter Kjaer has been a director of our company since July 1999 and is a representative of certain major investors in Hong Kong. Mr. Kjaer has been President and Chief Executive Officer of Jet-Asia Ltd., a Hong Kong-based aircraft and management company, since April 1996. From April 1989 to July 1996, Mr. Kjaer was the General Manager and a director of the Gallery of Contemporary Living Ltd., a Hong Kong-based art gallery.

Board Committees

The Board of Directors has an Audit and Finance Committee, Compensation Committee and Scientific Review Committee.

Audit and Finance Committee. The Audit and Finance Committee provides assistance to the Board of Directors in satisfying its fiduciary responsibilities relating to our accounting, auditing, operating and reporting practices, and reviews our annual financial statements, the selection and work of our independent auditors and the adequacy of internal controls for compliance with corporate policies and directives. The Audit and Finance Committee consists of Mr. Kjaer, Dr. Sullivan and Mr. Mangano.

Compensation Committee. The Compensation Committee:

- reviews general programs of compensation and benefits for all of our employees;
- makes recommendations to the Board of Directors concerning matters as compensation to be paid to our officers and directors; and
- administers our stock option plan, pursuant to which stock options may be granted to our eligible employees, officers, directors and consultants.

The Compensation Committee consists of Dr. Sullivan, Mr. Morgenstern and Ms. Ho.

Scientific Review Committee. The Scientific Review Committee assists in evaluating potential new licenses or new products. The Scientific Review Committee consists of Dr. Sullivan, Mr. Holubow and Dr. Rosenow.

Director Compensation

We do not pay fees to our directors. We do, however, periodically compensate our directors through the granting of stock options. On January 1, 2001, we granted stock options to purchase 2,500 shares of common stock to each of our non-employee directors. These options have an exercise price of $6.70 per share, fully vest on January 1, 2002 and expire ten years from the date of grant. All directors are reimbursed for travel expenses for attending meetings of the Board of Directors and any Board committees.

Executive Compensation

The following table provides summary information concerning cash and non-cash compensation paid to or earned by our Chief Executive Officer and our executive officers, who received or earned cash and non-cash salary and bonus of more than $100,000, for the

fiscal year ended December 31, 2001.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation Salary ($)	Annual Compensation Bonus ($)	Long-Term Compensation Securities Underlying Options (#)	All Other Compensation ($)
Stephen M. Simes *Vice Chairman, President and Chief Executive Officer*	2001	$ 291,500	$ 131,175	71,406	$ 18,388(3)
	2000	275,000	150,000(1)	0	29,317(3)
	1999	248,917	125,000(2)	185,625	22,965(3)
Phillip B. Donenberg *Chief Financial Officer, Treasurer and Secretary*	2001	150,000	45,000	21,546	13,592(6)
	2000	127,000	42,000(4)	0	13,286(6)
	1999	110,000	33,000(5)	52,187	13,001(6)
Leah M. Lehman, Ph.D. *Vice President, Clinical Development*	2001	180,000	54,000	50,000	12,450(7)
	2000				
	1999				
Steven J. Bell, Ph.D. *Vice President, Research and Pre-Clinical Development*	2001	102,000	30,000	5,000	11,250(9)
	2000	91,521	26,000(8)	0	11,250(9)
	1999	85,313	10,000	12,500	6,500(9)
John E. Lee (10) *Former Vice President, Commercial Development*	2001	146,407			9,338(11)
	2000	70,833		50,000	81,470(11)
	1999				

(1) Represents a cash bonus of $75,000 and a stock bonus of 12,500 shares of common stock valued at $75,000.

(2)

Represents a cash bonus of $75,000 and a stock bonus of 16,385 shares of common stock valued at $50,000.

(3) Represents an auto allowance ($12,000 in 2001, $12,000 in 2000 and $12,000 in 1999), a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999) and insurance premiums and taxes associated with the premiums ($1,138 in 2001, $12,067 in 2000 and $5,965 in 1999).

(4) Represents a cash bonus of $30,000 and a stock bonus of 2,000 shares of common stock valued at $12,000.

(5) Represents a cash bonus of $25,000 and a stock bonus of 2,621 shares of common stock valued at $8,000.

(6) Represents an auto allowance ($7,200 in 2001, $7,200 in 2000 and $7,200 in 1999), a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999) and insurance premiums paid and taxes associated with the premiums ($1,142 in 2001, $836 in 2000 and $801 in 1999).

(7) Represents an auto allowance of $7,200 and a 401(k) matching contribution of $5,250.

(8) Represents a cash bonus of $20,000 and a stock bonus of 1,000 shares of common stock valued at $6,000.

(9) Represents an auto allowance ($6,000 in 2001, $6,000 in 2000 and $1,500 in 1999) and a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999).

(10) Mr. Lee was Vice President, Commercial Development from August 2000 to September 2001. Mr. Lee resigned as Vice President, Commercial Development on September 28, 2001.

(11) Represents an auto allowance ($5,400 in 2001 and $3,000 in 2000), a 401(k) matching contribution ($3,938 in 2001 and $2,188 in 2000) and relocation expenses and associated taxes of $76,282 in 2000.

Option Grants in Last Fiscal Year

The following tables summarize option grants and exercises during the fiscal year ended December 31, 2001 to or by each of the executive officers named in the Summary Compensation Table on page 57 and the potential realizable value of the options held by these persons at December 31, 2001.

	Individual Grants (1)			
Name	Number of Securities Underlying Options Granted(#)	Percent of Total Options Granted to Employees in Fiscal Year	Exercise Price Per Share	Expiration Date
Stephen M. Simes	71,406(2)	46.32%	$ 4.00	4/5/11
Phillip B. Donenberg	21,546(2)	13.98%	$ 4.00	4/5/11
Leah M. Lehman, Ph.D.	50,000(3)	32.44%	$ 6.70	12/31/10
Steven J. Bell, Ph.D.	5,000(4)	3.24%	$ 6.70	12/31/10
John E. Lee				

(1) All of the options granted to the individuals in this table were granted under our Amended and Restated 1998 Stock Option Plan.

(2) This option vests in equal quarterly installments over three years so long as the executive officer remains employed by us at that date. To the extent not already exercisable, this option becomes immediately exercisable in full upon certain changes in control of our company and remains exercisable for the remainder of its term.

(3) This option vests: (i) with respect to 7,460 shares on 6/30/2001 and 12/31/2001; (ii) 3,730 shares on 3/31/2002, 6/30/2002, 9/30/2002, 12/31/2002, 3/31/2003, 6/30/2003, 9/30/2003 and 12/31/2003; and (iii) 5,240 shares on 1/1/2004. To the extent not already exercisable, this option becomes immediately exercisable in full upon certain changes in control of our company and remains exercisable for the remainder of its term.

(4) This option vests in equal annual installments over three years so long as the executive officer remains employed by us at that date. To the extend not already exercisable, this option becomes immediately exercisable in full upon certain changes in control of our company and remains exercisable for the remainder of its term.

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

The following table summarizes the number and value of options held by each of the executive officers named in the Summary Compensation Table on page 57 at December 31, 2001. None of these executive officers exercised any stock options during 2001.

	Number of Securities Underlying Unexercised Options at December 31, 2001		Value of Unexercised In-the-Money Options at December 13, 2001(1)	
Name	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable**
Stephen M. Simes	287,725	69,305	$ 1,707,667	$ 328,536
Phillip B. Donenberg	87,337	20,396	$ 518,390	$ 95,934
Leah M. Lehman, Ph.D	14,920	35,080	$ 26,856	$ 63,144
Steven J. Bell, Ph.D.	25,000	5,000	$ 140,625	