COFFEE HOLDING CO INC Form SB-2/A October 25, 2004

Registration No. 333-116838

# U.S. Securities and Exchange Commission

Washington, D.C. 20549

Amendment No. 2

to

# FORM SB-2

## REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# Coffee Holding Co., Inc.

(Name of small business issuer in its charter)

#### Nevada

(State or other jurisdiction of incorporation or organization)

#### 2080

(Primary Standard Industrial Classification Code Number)

#### 11-2238111

(I.R.S. Employer Identification No.)

4401 First Avenue, Brooklyn, New York 11232-0005 (718) 832-0800

(Address and telephone number of principal executive offices)
(Address of principal place of business or intended principal place of business)

Andrew Gordon
President and Chief Executive Officer
4401 First Avenue
Brooklyn, New York 11232-0005
(Name and address, and telephone of agent for service)

With copies to:

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Approximate date of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

#### **CALCULATION OF REGISTRATION FEE**

Title of Each Class of		Proposed Maximum Offering	Proposed Maximum	
Securities to be Registered	Amount to be registered (1)	Price Per Share (2)	Aggregate Offering Price (2)	Amount of Registration Fee

Common Stock, \$ 0.001 par value	1,840,000	\$ 6.00	\$ 11,040,000	\$ 1,399
Warrants(3)	160,000	\$ .000625	\$ 100	\$ 1
Common Stock, \$0.001 par value(4)	160,000	\$ 6.60	\$ 1,056,000	\$ 134
Total			\$ 12,096,100	\$ 1,534(5)

- (1) Includes the maximum number of shares that may be issued in connection with this offering.
- (2) Estimated solely for the purpose of calculating the registration fee.
- (3) To be issued to the underwriter.
- (4) Issuable upon exercise of the underwriter

  s warrants. Pursuant to Rule 416 under the Securities Act of 1933, as amended, also includes such additional shares of common stock as may become issuable pursuant to the anti-dilution provision of the warrants.
- (5) A fee in the amount of \$1,534 has been previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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#### Subject to Completion, Dated October 25, 2004

#### **PROSPECTUS**

# 1,600,000 Shares

# **COFFEE HOLDING CO., INC.**

# **Common Stock**

This is our initial public offering of shares of common stock. We are offering 1,600,000 shares of our common stock.

While we have been filing reports under the Securities Exchange Act of 1934, there currently is no public market for our common stock. We currently anticipate that the initial public offering price will be between \$5.00 per share and \$6.00 per share. We have applied to have our common stock listed on the American Stock Exchange under the symbol <code>\_JVA.\_</code> See <code>\_Underwriting\_</code> for information relating to the factors considered in determining the initial public offering price.

Investing in our common stock involves a high degree of risk. Please read the [Risk Factors] beginning on page 6. You will experience immediate and substantial dilution.

Public offering price \$
Underwriting discounts \$
Proceeds to Coffee Holding \$

We have granted the underwriter a 45 day option to purchase up to 240,000 additional shares of common stock on the same terms and conditions as set forth above, solely to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Maxim Group LLC expects to deliver the shares on or about \_\_\_\_\_, 2004.

## MAXIM GROUP LLC

The date of this prospectus is \_\_\_\_\_, 2004

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

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Until \_\_\_\_\_\_, 2004, 25 days after the date of this offering, all dealers that effect transactions in our shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer sobligations to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

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#### PROSPECTUS SUMMARY

This summary highlights material information about us that is described more fully elsewhere in this prospectus. It may not contain all of the information that you find important. You should carefully read this entire document, including the "Risk Factors" section beginning on page 6 and our financial statements and their related notes before making a decision to invest in our common stock. Unless otherwise indicated, the information in this prospectus assumes that the underwriter will not exercise its over-allotment option.

#### **General Overview**

**Products and Operations.** We are an integrated wholesale coffee roaster and dealer in the United States and one of the few coffee companies that offers a broad array of coffee products across the entire spectrum of consumer tastes, preferences and price points. Our core products can be divided into three categories:

Wholesale Green Coffee: unroasted raw beans imported from around the world and sold to large and small roasters and coffee shop operators;
<b>Private Label Coffee:</b> coffee roasted, blended, packaged and sold under the specifications and names of others, including supermarkets that want to have their own brand name on coffee to compete with national brands; and
<b>Branded Coffee:</b> coffee roasted and blended to our own specifications and packaged and sold under our seven brand names in different segments of the market.

Our private label and branded coffee products are sold throughout the United States and Canada to supermarkets, wholesalers, and individually owned and multi-unit retail customers. Our unprocessed green coffee, which includes over 70 types of coffee from all over the world, is sold to specialty gourmet roasters.

*Geographic Expansion.* In February 2004, we acquired certain assets of Premier Roasters, a roaster-dealer located in La Junta, Colorado, for \$825,000. We are using the purchased assets to expand our integrated wholesale coffee roaster and dealer operations in the Western United States.

#### Financial Highlights.

Net sales increased 28% for the nine months ended July 31, 2004 compared to the nine months ended July
31, 2003, from approximately \$14,486,000 to approximately \$18,578,000 and 16% for the year ended
October 31, 2003 compared to the year ended October 31, 2002 from approximately \$17,433,000 to
approximately \$20,240,000;

Net income increased 39% for the nine months ended July 31, 2004 compared to the nine months ended
July 31, 2003 from approximately \$441,000 to approximately \$613,000 and decreased 18% for the year
ended October 31, 2003 compared to the

	year ended October 31, 2002 from approximately \$755,000 to approximately \$622,000;
	We increased our overall annual coffee poundage volume from 13 million pounds in 1998 to 17.4 million pounds in 2003;
	We continued to be profitable through varying cycles of the coffee commodity market. From fiscal years 2001 to 2003, when coffee commodity prices were trading at 30-year lows, our net income was approximately \$518,000, \$755,000, and \$622,000, respectively; and
[] Our (	Since 1998, we increased the number of our specialty green coffee customers, including coffee houses, single store operators, mall coffee stores and mail order sellers, by 81% from 150 to 272.  Competitive Strengths
То	achieve our growth objectives described below, we intend to leverage the following competitive strengths:
	<b>National Distribution with Capacity For Growth.</b> Since 1991, we have been able to expand our distribution to a national platform while operating from only our East Coast location. We have recently made capital investments to improve our roasting, packaging and fulfillment infrastructure to support the production and distribution of large quantities of fresh coffee products throughout the United States. We believe that our new La Junta, Colorado facility will allow us to continue to grow our business by further increasing our presence in the Western United States.
	<b>Positioned to Profitably Grow Through Varying Cycles of the Coffee Market.</b> While many of our competitors engage in distinct segments of the coffee business, we sell retail branded coffee, retail private label coffee, wholesale specialty green and whole bean coffees, food service coffees, instant coffees and niche products. Our branded and private label roasted ground coffees are sold predominantly at competitive and value price levels and some of our other branded and specialty gourmet coffees are sold predominantly at the premium price levels. We believe that our profitability is not dependent on any one product or price segment of the coffee industry and, therefore, is less sensitive than our competition to potential coffee commodity price and overall economic volatility.
	Wholesale Green Coffee Market Presence. We believe that our relationships with wholesale green coffee customers and our focus on selling green coffee as a wholesaler

has enabled us to participate in the growth of the specialty coffee market while mitigating the risks associated with the competitive retail specialty coffee environment.

	Diverse Portfolio of Differentiated Branded Coffees. We have amassed a portfolio of five proprietary name brands sold to supermarkets, wholesalers and individually-owned stores in the United States, including brands for specialty espresso, Latin espresso, Italian espresso, 100% Colombian coffee and blended coffee. In addition, we have entered into a licensing agreement with Del Monte Corporation for the exclusive right to use the S&W and IL CLASSICO trademarks in the United States and other countries approved by Del Monte Corporation in connection with the production, manufacture and sale of roasted whole bean and ground coffee for distribution to retail customers. Our existing portfolio of differentiated brands combined with our management expertise serve as a platform to add additional name brands through acquisition or licensing agreements which target product niches and segments that do not compete with our existing brands.
_	Management Has Extensive Experience in the Coffee Industry. We have been a family operated business for three generations. Throughout this time, we have remained profitable through varying cycles in the coffee industry and the economy. Our founder, Sterling Gordon, has over 50 years of experience in the coffee business during which time he has developed a reputation in the industry as an expert in coffee blending and quality. Andrew Gordon and David Gordon have worked with Coffee Holding for 21 and 23 years, respectively.
We	believe that significant growth opportunities exist by:

<b>Selectively Pursuing Strategic Acquisitions and Alliances.</b> We intend to expand our operations by acquiring coffee companies, seeking strategic alliances and acquiring or licensing brands which complement our business objectives. Consistent with this strategy, in February 2004, we acquired certain assets of Premier Roasters. We intend to further expand the market presence of our branded products outside our primary Northeastern United States market through other acquisitions and strategic alliances.
<i>Growing Our Café Caribe Product.</i> We believe there is significant opportunity for our Café Caribe brand to gain market share among Hispanic consumers in the United States. Café Caribe is a specialty espresso coffee that targets espresso coffee drinkers. We intend to use a portion of the proceeds of this offering to

Furthering the Market Penetration of Our Niche Products. We intend to capture additional market share through our existing distribution channels by selectively adding or introducing new brand names and products across multiple price points, including: specialty blends; private label "value" blends and trial-sized mini-brick packages; specialty instant coffees; instant cappuccinos and hot chocolates; and tea line products.

marketing campaign designed to increase our brand awareness in existing markets.

increase the sales of this brand and other espresso-based products by implementing a branded sales and

Developing Our Food Service Business. We plan to expand further into the food service business by developing new distribution channels for our products. We intend to use a portion of the proceeds of this offering to grow our food service distribution both organically and through acquisitions.

## **Principal Executive Office**

Our address is 4401 First Avenue, Brooklyn, New York 11232-0005. Our telephone number is 718-832-0800. We maintain a website at www.coffeeholding.com. Information contained on our website does not constitute part of this prospectus.

We were originally incorporated in New York in 1971. Pursuant to an Agreement and Plan of Merger between us and Transpacific International Group Corp., we merged with and into Transpacific International Group Corp. in February, 1998, with Transpacific being the surviving corporation. After the merger, Transpacific changed its name to Coffee Holding Co., Inc.

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## The Offering

Common stock offered 1,600,000 shares

Common stock outstanding 5,599,650 shares after the offering(1)

Use of proceeds We intend to use the proceeds of this offering to repay

approximately \$1.8 million of indebtedness, to purchase equipment for our La Junta, Colorado facility, to implement a branded sales and marketing campaign and for general corporate purposes, including working capital and capital expenditures. As strategic opportunities arise, we may use the proceeds of this

offering to fund acquisitions, licensing and other strategic alliances. See "Use of Proceeds."

Proposed American Stock Exchange symbol Currently, no public market for our common stock

exists. We have applied to have our common stock listed on the American Stock Exchange under the symbol  $\prod VA.$ 

Risk factors

The securities offered by this prospectus are speculative

and involve a high degree of risk and investors purchasing securities will experience immediate and substantial dilution and should not purchase the securities unless they can afford the loss of their entire investment. See "Risk Factors" beginning on page 6.

<sup>(1)</sup> This number does not include 800,000 shares reserved for issuance upon exercise of options eligible for grant under the Coffee Holding Co., Inc. 1998 Stock Option Plan, for which no options have yet been granted, or 160,000 shares of our common stock underlying warrants to be issued to the underwriter.

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## **Summary Financial Information**

The summary financial data for the fiscal years ended October 31, 2003, 2002 and 2001 was derived from our financial statements that have been audited by Lazar Levine & Felix LLP for the respective periods. The information for the nine months ended July 31, 2004 and 2003 was derived from unaudited financial data but, in the opinion of management, reflects all adjustments necessary for a fair presentation of the results for such periods. The summary financial and other data presented below should be read in conjunction with, and is qualified in its entirety by, our audited financial statements and related notes appearing in this prospectus beginning on page F-1. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our financial statements for the years ended October 31, 2003 and 2002 and for the nine months ended July 31, 2004 and 2003.

	For the Year Ended						For the Nine Months Ended			
		October 31, 2003		October 31, 2002		October 31, 2001		July 31, 2004		July 31, 2003
		(D	olla	rs in thou	saı	nds, excep	t p	er share d	ata)	)
<b>Income Statement Data:</b>										
Net sales	\$	20,240	\$	17,433	\$	20,327	\$	18,578	\$	14,486
Cost of sales		15,373		12,453		16,065		13,893		10,887
Gross profit		4,867		4,980		4,262		4,685		3,599
Operating expenses		3,993		3,505		3,162		3,462		2,761
Income from operations		874		1,475		1,100		1,223		838
Other income (expense)		(136)		(162)		( 269)		(128)		(99)
Income before income taxes		738		1,313		831		1,095		739
Provision for income taxes		116		558		313		482		298
Net income	\$	622	\$	755	\$	518	\$	613	\$	441
Net income per share □ basic and diluted	\$	.16	\$	.19	\$	.13	\$	.15	\$	.11
Book value per share	\$	.53	\$	.37	\$	.19	\$	.68	\$	.48

	At October 31,							At July 31, 2004				
	 2003	2002		2001			Actual	As Adjusted(1)				
	(Dollars in thousands)											
Balance Sheet Data:												
Total assets	\$ 7,035	\$	6,042	\$	5,713	\$	8,387	\$	13,927			
Short-term debt	\$ 2,076	\$	2,483	\$	2,090	\$	5,426	\$	3,815			
Long-term debt	\$ 2,839	\$	2,061	\$	2,880	\$	228	\$	39			
Total liabilities	\$ 4,915	\$	4,544	\$	4,970	\$	5,654	\$	3,854			
Shareholders' equity	\$ 2,120	\$	1,498	\$	743	\$	2,733	\$	10,073			
(1)												

Adjusted to give effect to the receipt and application of the net proceeds of approximately \$7,340,000 from the sale of common shares offered by this prospectus at an assumed initial public offering price of \$5.50 per share.

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#### **RISK FACTORS**

An investment in our common stock is speculative and involves a high degree of risk. You should carefully consider the risks described below before buying our common stock. These risks could have a material adverse effect on our business, financial condition and results of operations and the value of our common stock.

#### Risk Factors Affecting Our Company

Our business is centered on essentially one commodity; coffee. Our operations have primarily focused on the

Because our business is highly dependent upon a single commodity, coffee, any decrease in demand for coffee could materially adversely affect our revenues and profitability.

follow	ing areas of the coffee industry:
	the roasting, blending, packaging and distribution of private label coffee;
	the roasting, blending, packaging and distribution of proprietary branded coffee; and
	the sale of wholesale specialty green coffee.
Dema	nd for our products is affected by:
	consumer tastes and preferences;
	national, regional and local economic conditions;
	demographic trends; and
than i	the type, number and location of competing products. cause we rely on a single commodity, any decrease in demand for coffee would harm our business more f we had more diversified product offerings and could materially adversely affect our revenues and ting results.
	are unable to geographically expand our branded and private label products, our growth will be ded which could result in reduced sales and profitability.
produ	r business strategy emphasizes, among other things, geographic expansion of our branded and private label cts as opportunities arise. We may not be able to implement successfully this portion of our business gy. Our ability to implement this portion of our business strategy is dependent on our ability to:
	market our products on a national scale;
	increase our brand recognition on a national scale;
	enter into distribution and other strategic arrangements with third party retailers; and

manage growth in administrative overhead and distribution costs likely to result from the planned expansion of our distribution channels.
Our sales and profitability may be adversely affected if we fail to successfully expand the geographic distribution of our branded and private label products. In addition, our expenses could increase and our profits could decrease as we implement our growth strategy.
Any inability to successfully implement our strategy of growth through selective acquisitions, licensing arrangements and other strategic alliances could materially affect our revenues and profitability.
Our strategy of growth through the selective acquisition of coffee companies, the selective acquisition or licensing of additional coffee brands and other strategic alliances presents risks that could result in increased expenditures and could materially adversely affect our revenues and profitability, including:
□ such acquisitions, licensing arrangements or other strategic alliances may divert our management□s attention from our existing operations;
we may not be able to successfully integrate any acquired coffee companies or new coffee brands into our existing business;
we may not be able to manage the contingent risks associated with the past operations of, and other unanticipated problems arising in, any acquired coffee company; and
<ul> <li>we may not be able to control unanticipated costs associated with such acquisitions, licensing arrangements or strategic alliances.</li> <li>In addition, any such acquisitions, licensing arrangements or strategic alliances may result in:</li> </ul>
potentially dilutive issuances of our equity securities; and
the incurrence of additional debt. As has been our practice in the past, we will continuously evaluate any such acquisitions, licensing opportunities or strategic alliances. However, we have not reached any agreement or arrangement with respect to any such acquisition, licensing opportunity or strategic alliance as of the date of this prospectus and we may not be able to consummate any acquisitions, licensing arrangements or strategic alliances on terms favorable to us or at all. The failure to consummate any such acquisitions, licensing arrangements or strategic alliances may reduce our growth and expansion.
The loss of any of our key customers could negatively affect our revenues and decrease our earnings.
We are highly dependant upon sales of our private label and branded coffee to two wholesalers, Supervalu an Topco/Shurfine, and upon sales of wholesale green coffee to one

customer, Green Mountain Coffee Roasters. Sales to Supervalu, Topco/Shurfine, and Green Mountain Coffee Roasters accounted for approximately 16.1%, 7.5%, and 15.6% of our net sales for the fiscal year ended October 31, 2003 and 9.2%, 6.5%, and 21.2% for the nine months ended July 31, 2004, respectively. Although no other customer accounted for greater than 5% of our consolidated net revenues during these periods, other customers may account for more than 5% of our consolidated net revenues in future periods. We do not have long-term contracts with these or any of our customers. Accordingly, our customers can stop purchasing our products at any time without penalty and are free to purchase products from our competitors. The loss of, or reduction in sales to, customers such as Supervalu, Topco/Shurfine, Green Mountain Coffee Roasters or any of our other customers to which we sell a significant amount of our products or any material adverse change in the financial condition of such customers would negatively affect our revenues and decrease our earnings.

# If we lose our key personnel, including Andrew Gordon and David Gordon, our revenues and profitability could suffer.

Our success depends to a large degree upon the services of Andrew Gordon, our President, Chief Executive Officer and Treasurer, and David Gordon, our Executive Vice President-Operations and Secretary. We also depend to a large degree on the expertise of our coffee roasters. We do not have employment contracts with our coffee roasters. Our ability to source and purchase a sufficient supply of high quality coffee beans and to roast coffee beans consistent with our quality standards could suffer if we lose the services of any of these individuals. As a result, our business and operating results would be adversely affected. We may not be successful in obtaining and retaining a replacement for either Andrew Gordon or David Gordon if they elect to stop working for us. In addition, we do not have key-man insurance on the lives of Andrew Gordon or David Gordon.

# If our hedging policy is not effective, we may not be able to control our coffee costs, we may be forced to pay greater than market value for green coffee and our profitability may be reduced.

The supply and price of coffee beans are subject to volatility and are influenced by numerous factors which are beyond our control. Historically, we have used short-term coffee futures and options contracts primarily for the purpose of partially hedging and minimizing the effects of changing green coffee prices and to reduce our cost of sales. In addition, during the latter half of fiscal 2000, we began to acquire futures contracts with longer terms, generally three to six months, primarily for the purpose of guaranteeing an adequate supply of green coffee. Realized and unrealized gains or losses on futures contracts are accounted for in cost of sales. Gains on futures contracts reduce cost of sales and losses on futures contracts increase cost of sales. Gains on futures contracts were \$868,669 and \$778,410 for the years ended October 31, 2003 and 2002, respectively, and were \$720,297 for the nine months ended July 31, 2004. Although the use of these derivative financial instruments has enabled us to mitigate the effect of changing prices, no strategy is effective to eliminate the pricing risks and we generally remain exposed to loss when prices decline significantly in a short period of time, and we generally remain exposed to supply risk in the event of non-performance by the counter-parties to any futures contracts. Although we generally have been able to pass green coffee price increases through to customers, thereby maintaining our gross profits, we may not be able to pass price

increases through to our customers in the future. Our hedging strategy and the hedges that we enter into may not adequately offset the risks of coffee bean price volatility and our hedges may result in losses. Failure to properly design and implement an effective hedging strategy may materially adversely affect our business and operating results. In this case, our costs of sales may increase, resulting in a decrease in profitability.

If our planned increase in marketing expenditures fails to promote and enhance our brands, the value of our brands could decrease and our revenues and profitability could be adversely affected.

We believe that promoting and enhancing our brands is critical to our success. We intend to increase our marketing expenditures to increase awareness of our brands, which we expect will create and maintain brand loyalty. If our brand-building strategy is unsuccessful, these expenses may never be recovered, and we may be unable to increase awareness of our brands or protect the value of our brands. If we are unable to achieve these goals, our revenues and ability to implement our business strategy could be adversely affected.

Our success in promoting and enhancing our brands will also depend on our ability to provide customers with high quality products and service. Although we take measures to ensure that we sell only fresh roasted coffee, we have no control over our coffee products once they are purchased by our wholesale customers. Accordingly, wholesale customers may store our coffee for longer periods of time or resell our coffee without our consent, in each case, potentially affecting the quality of the coffee prepared from our products. Although we believe we are less susceptible to quality control problems than many of our competitors because a majority of our products are sold in cans or brick packs unlike whole bean coffees, if consumers do not perceive our products and service to be of high quality, then the value of our brands may be diminished and, consequently, our operating results and ability to implement our business strategy may be adversely affected.

Our roasting methods are not proprietary, so competitors may be able to duplicate them, which could harm our competitive position. If our competitive position is weakened, our revenues and profitability could be materially adversely affected.

We consider our roasting methods essential to the flavor and richness of our roasted coffee and, therefore, essential to our brands of coffee. Because we do not hold any patents for our roasting methods, it may be difficult for us to prevent competitors from copying our roasting methods if such methods become known. If our competitors copy our roasting methods, the value of our coffee brands may be diminished, and we may lose customers to our competitors. In addition, competitors may be able to develop roasting methods that are more advanced than our roasting methods, which may also harm our competitive position.

Our operating results may fluctuate significantly, which makes our results of operations difficult to predict and could cause our results of operations to fall short of expectations.

Our operating results may fluctuate from quarter to quarter and year to year as a result of a number of factors, many of which are outside of our control. These fluctuations could be caused by a number of factors including:

	fluctuations in purchase prices and supply of green coffee;
	fluctuations in the selling prices of our products;
	the level of marketing and pricing competition from existing or new competitors in the coffee industry;
	our ability to retain existing customers and attract new customers; and
As a meaning our op	our ability to manage inventory and fulfillment operations and maintain gross margins. a result of the foregoing, period-to-period comparisons of our operating results may not necessarily be negful and those comparisons should not be relied upon as indicators of future performance. Accordingly erating results in future quarters may be below market expectations. In this event, the price of our on stock may decline.

Since we rely heavily on common carriers to ship our coffee on a daily basis, any disruption in their services or increase in shipping costs could adversely affect our relationship with our customers, which could result in reduced revenues, increased operating expenses, a loss of customers or reduced profitability.

We rely on a number of common carriers to deliver coffee to our customers and to deliver coffee beans to us. We consider roasted coffee a perishable product and we rely on these common carriers to deliver fresh roasted coffee on a daily basis. We have no control over these common carriers and the services provided by them may be interrupted as a result of labor shortages, contract disputes and other factors. If we experience an interruption in these services, we may be unable to ship our coffee in a timely manner, which could reduce our revenues and adversely effect our relationship with our customers. In addition, a delay in shipping could require us to contract with alternative, and possibly more expensive, common carriers and could cause orders to be cancelled or receipt of goods to be refused. Any significant increase in shipping costs could lower our profit margins or force us to raise prices, which could cause our revenue and profits to suffer.

#### If we are unable to obtain additional financing, we may not be able to fund and grow our operations.

We anticipate, but cannot assure you, that we will be able to expand our operations and implement our growth strategy in fiscal 2004 through the proceeds of this offering, cash provided by operating activities and borrowings under the credit facility with Wells Fargo Business Credit. This expectation assumes that we will be able to generate a sufficient level of sales in order to increase income, eligible accounts receivable and inventory to permit advances

under our line of credit facility. In the event our expectations are not fulfilled or that we are unable to generate sufficient amounts of cash to implement our growth strategy, we may be required to seek additional financing. We have no current arrangements for additional financing and additional financing may not be available to us on commercially reasonable terms, or at all. If we are not successful in obtaining additional financing, we might not be able to implement our expansion plans.

If there was a significant interruption in the operation of either one of our facilities, we may not have the capacity to service all of our customers and we may not be able to service our customers in a timely manner, thereby reducing our revenues and earnings.

Even though we recently acquired a second coffee roasting and distribution facility, a significant interruption in the operation of either facility, whether as a result of a natural disaster or other causes, could significantly impair our ability to operate our business. Due to manufacturing and logistical efficiencies, our New York facility generally services customers in the Northeastern United States and the Midwest United States and our La Junta, Colorado facility services customers in the Western United States. If there was a significant interruption in the operation of either one of our facilities, we may not have the capacity to service all of our customers out of the lone operating facility and we may not be able to service our customers in a timely manner. As a result, our revenues and earnings would be materially adversely affected.

## Risk Factors Relating to the Coffee Industry

Increases in the cost of high quality Arabica or Robusta coffee beans could reduce our gross margin and profit.

Co	offee is a traded commodity and, in general, its price can fluctuate depending on:
	weather patterns in coffee-producing countries;
	economic and political conditions affecting coffee-producing countries, including acts of terrorism in such countries;
	foreign currency fluctuations; and
profit produ incre throu We m	trade regulations and restrictions between coffee-producing countries and the United States. the cost of wholesale green coffee increases due to any of these factors, our margins could decrease and our ability could suffer accordingly. Although we have historically attempted to raise the selling prices of our acts in response to increases in the price of wholesale green coffee, when wholesale green coffee prices ase rapidly or to significantly higher than normal levels, we are not always able to pass the price increases up to our customers on a timely basis, if at all, which adversely affects our operating margins and cash flow may not be able to recover any future increases in the cost of wholesale green coffee. Even if we are able to the future increases, our operating margins and results of operations
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may still be materially and adversely affected by time delays in the implementation of price increases.

# Disruptions in the supply of green coffee could result in a deterioration of our relationship with our customers, decreased revenues or could impair our ability to grow our business.

Green coffee is a commodity and its supply is subject to volatility beyond our control. Supply is affected by many factors in the coffee growing countries including weather, political and economic conditions, acts of terrorism, as well as efforts by coffee growers to expand or form cartels or associations. If we are unable to procure a sufficient supply of green coffee, our sales would suffer.

Some of the arabica coffee beans of the quality we purchase do not trade directly on the commodity markets. Rather, we purchase the high end arabica coffee beans that we use on a negotiated basis. We depend on our relationships with coffee brokers, exporters and growers for the supply of our primary raw material, high quality Arabica coffee beans. If any of our relationships with coffee brokers, exporters or growers deteriorate, we may be unable to procure a sufficient quantity of high quality coffee beans at prices acceptable to us or at all. In such case, we may not be able to fulfill the demand of our existing customers, supply new retail stores or expand other channels of distribution. A raw material shortage could result in a deterioration of our relationship with our customers, decreased revenues or could impair our ability to expand our business.

# The coffee industry is highly competitive and if we cannot compete successfully, we may lose our customers or experience reduced sales and profitability.

The coffee markets in which we do business are highly competitive and competition in these markets is likely to become increasingly more intense due to the relatively low barriers to entry. The industry in which we compete is particularly sensitive to price pressure, as well as quality, reputation and viability for wholesale and brand loyalty for retail. To the extent that one or more of our competitors becomes more successful with respect to any key competitive factor, our ability to attract and retain customers could be materially adversely affected. Our private label and branded coffee products compete with other manufacturers of private label coffee and branded coffees. These competitors, such as Kraft General Foods, Inc., The Kroger Co., The Procter & Gamble Company and Sara Lee Corporation, have much greater financial, marketing, distribution, management and other resources than we do for marketing, promotions and geographic and market expansion. In addition, there are a growing number of specialty coffee companies who provide specialty green coffee and roasted coffee for retail sale. If we are unable to compete successfully against existing and new competitors, we may lose our customers or experience reduced sales and profitability.

## Adverse public or medical opinion about caffeine may reduce our sales and profits.

Some of our coffee products contain caffeine and other active compounds, the health effects of which are not fully understood. A number of research studies conclude or suggest that excessive consumption of caffeine may lead to an increased heart rate, restlessness and anxiety, depression, headaches, sleeplessness and other adverse health effects. An unfavorable report on

the health effects of caffeine or other compounds present in coffee could significantly reduce the demand for coffee, which could reduce our sales and profits.

#### Risk Factors Related to this Offering

# The Gordon family effectively controls Coffee Holding, substantially reducing the influence of our other stockholders.

Andrew Gordon and David Gordon, executive officers and directors of Coffee Holding, beneficially own approximately 31.0% of our outstanding shares of common stock. In addition, other members of the Gordon family beneficially own an additional 55.5% of the outstanding shares of common stock. After the offering, Andrew Gordon, David Gordon and other members of the Gordon family will beneficially own approximately 61.8% of our outstanding common stock and will be able to control the vote on all matters submitted to a vote of stockholders, including the election of directors, amendments to the Articles of Incorporation and Bylaws and approval of significant corporate transactions. This control could have the effect of discouraging, delaying or preventing a change in our control which other stockholders might consider favorable. This control could also have the effect of approving a change in our control on terms which other stockholders might consider unfavorable.

# We intend to implement anti-takeover provisions which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

We intend to amend our Articles of Incorporation to, among other things, include provisions which could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

establishing a classified board of directors requiring that members of the board be elected in different years;
authorizing the issuance of [blank check] preferred stock that could be issued by our board of directors to increase the number of outstanding shares or change the balance of voting control and resist a takeover attempt;
prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
limiting the ability of stockholders to call special meetings of stockholders;
prohibiting stockholder action by written consent and requiring all stockholder actions to be taken at a meeting of our stockholders; and
establishing advance notice requirements for nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at stockholder meetings. addition, provisions of the Nevada Revised Statutes and the terms of the employment agreements with our tive officers may discourage, delay or prevent a change in our control.
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# Sales of substantial amounts of our common stock may occur after this offering, which could cause our stock price to fall.

Our current stockholders hold a substantial number of shares, which they will be able to sell in the public market in the near future. Upon the completion of this offering (and excluding shares underlying the underwriter | s warrants), we will have 5,599,650 shares of common stock issued and outstanding (5,839,650 shares if the underwriter\s over-allotment option is exercised in full). Of those shares, the 1,600,000 sold in this offering (1,840,000 if the underwriter\s over-allotment option is exercised in full) and the 29,650 shares registered in the Rule 419 Offering will have been registered under the Securities Act of 1933, as amended, and may be resold without further registration and 3,970,000 shares are ∏restricted securities∏ and may not be sold unless the sale is registered under the Securities Act or pursuant to an exemption from registration under the Securities Act. All of these restricted securities (including 1,239,200 held by our officers and directors and an additional 2,220,200 shares owned by members of the Gordon family who are not our officers or directors) are eligible for sale under the exemption provided by Rule 144 of the Securities Act. Approximately 3,540,400 shares will be subject to lock-up agreements which prohibit the sale of the shares for nine months after this offering. However, it is possible that the underwriter could waive the nine-month lock-up period, if, for example, the underwriter determines that the market price of our common stock has reached a sufficiently stable point that it could bear the sale of shares subject to the lock-ups. Sales of a substantial number of shares of our common stock within a short period of time after this offering could cause our stock price to fall. In addition, the sale of these shares could impair our ability to raise capital through the sale of additional stock.

# There has been no prior market for our common stock and if an active trading market for our stock does not develop or if our stock is delisted from the American Stock Exchange, you may have difficulty selling your stock.

Prior to the offering, there has been no public trading market for our common stock. Furthermore, given the minimal number of outstanding shares of common stock held by our non-affiliates, a liquid public market may not develop. We have applied for listing of our common stock on the American Stock Exchange under the symbol  $\Pi VA$ .

The development of an active trading market depends on the existence of willing buyers and sellers, the presence of which is not within our control, or the control of any market maker or specialist. The number of active buyers and sellers of our common stock at any particular time may be limited. Under such circumstances, you could have difficulty selling your shares on short notice, and, therefore, you should not view our common stock as a short-term investment. An active trading market for our securities might not develop or be sustained. In addition, even if these securities are listed and traded initially on the American Stock Exchange, we may fail to meet certain minimum standards for continued listing. In that event, our common stock could be delisted, and our common stock would no longer be listed, if we are unable to list our common stock on another trading market. This may make it extremely difficult to sell or trade our common stock.

We will have discretion as to the use of the proceeds of this offering. If we do not use the proceeds effectively, we may not be able to successfully implement our business strategy which could impede our growth and reduce our sales and profitability.

We intend to use the proceeds of this offering to repay approximately \$1.8 million of indebtedness, to purchase equipment for our La Junta, Colorado facility, to implement a branded sales and marketing campaign and for general corporate purposes, including working capital and capital expenditures. As strategic opportunities arise, we may use the proceeds of this offering to fund acquisitions, licensing and other strategic alliances. We will have broad discretion in applying the portion of the net proceeds reserved for general corporate purposes and may use the proceeds in ways that are not optimal or with which the stockholders disagree. Accordingly, investors in this offering will be relying on management's judgment with only limited information about our specific intentions regarding a significant portion of the use of proceeds.

#### You will incur immediate and substantial dilution.

You will experience an immediate and substantial dilution of \$3.70 per share (\$3.58 per share assuming exercise of the underwriter's over-allotment option) in the net tangible book value per share of common stock based on an assumed initial public offering price of \$5.50 per share. New investors and existing stockholders will have paid 91.0% and 9.0%, respectively, of the total consideration paid for the shares of our common stock outstanding after this offering. Accordingly, existing stockholders will benefit disproportionately from this offering. If we raise additional capital through the sale of equity, including preferred stock or convertible securities, your percentage of ownership will be diluted. You may also experience dilution if stock options or warrants to purchase our shares are exercised. As of the date of this prospectus, we had reserved 800,000 shares of our common stock for issuance under our 1998 Stock Option Plan and 160,000 shares of our common stock for issuance upon the exercise of warrants to be issued to the underwriter at the completion of this offering. No other options or warrants had been granted or exercised as of the date of this prospectus.

If our common stock is deemed to be a <code>[penny stock,[]</code> it may be subject to special requirements or conditions that could make it more difficult for you to sell your stock. This could cause our stock price to decline.

If the trading price of our common stock drops below \$5.00 per share and our common stock ceases to be listed on the American Stock Exchange or other comparable national exchange, our common stock may be deemed to be  $\lceil penny \ stock. \rceil$  Penny stocks are stocks:

With a price of less than \$5.00 per share;
Not traded on a □recognized□ national exchange;
Whose prices are not quoted on the Nasdaq automated quotation system; or
In issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation
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for less than three years), or with average revenues of less than \$6.0 million for the last three years.

Broker/dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stocks. Moreover, broker/dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor. These requirements may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to resell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Forward-looking statements typically are identified by use of terms such as <code>[may,[]]should,[][plan,[]]expect,[][anticipate,[]]estimate[]</code> and similar words, although some forward-looking statements are expressed differently. Forward-looking statements represent our management[]s judgment regarding future events. Although we believe that the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. All statements other than statements of historical fact included in this prospectus regarding our financial position, business strategy, products, products under development, markets, budgets, plans, or objectives for future operations are forward-looking statements. We cannot guarantee the accuracy of the forward-looking statements, and you should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including the statements under <code>[Risk Factors]</code> set forth above.

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#### USE OF PROCEEDS

We estimate that the net proceeds to us from the offering will be approximately \$7.3 million, or \$8.5 million if the underwriter exercises its over-allotment option in full, assuming an initial public offering price of \$5.50 per share and after deducting the underwriting discounts and commissions of approximately \$880,000, or \$1.0 million if the underwriter exercises its over-allotment option in full, and estimated offering expenses of approximately \$580,000 or \$619,600 if the underwriter exercises its over-allotment option in full payable by us.

We intend to use the net proceeds of this offering as follows:
 approximately \$1.8 million to repay indebtedness under our revolving line of credit and term loan;
 approximately \$1.65 million to purchase equipment for our La Junta, Colorado facility that will allow us to increase production and expand our product offerings on the West Coast;
 approximately \$1.5 million implement a branded sales and marketing campaign designed to increase our brand awareness in existing markets, including targeting Hispanic consumers throughout the United States; and
 the remaining \$2.35 million for general corporate purposes, including working capital and capital expenditures.

The \$1.8 million indebtedness that we intend to repay using proceeds of this offering includes approximately \$1.53 million of obligations under our revolving line of credit and approximately \$273,000 of obligations under the term loan. Our credit facility with Wells Fargo Business Credit provides for a revolving line of credit of up to \$5,000,000 based on eligible trade accounts receivable and inventories and a term loan of up to \$750,000 based on eligible equipment through November 20, 2004. Interest on the line of credit is payable monthly at the prime rate plus .25% (an effective rate of 4.75% at September 30, 2004) and interest on the term loan is payable monthly at the prime rate plus .50% (an effective rate of 5.00% at September 30, 2004). Principal payments on the term loan are payable in monthly installments of \$7,000.

The foregoing represents our best estimate of our allocation of the net proceeds of this offering. This estimate is based on certain assumptions related to our sales and marketing activities, the growth of our business, competition and other factors. Future events, as well as changes in economic or competitive conditions or our business and the results of our sales and marketing activities and growth of our business, may make shifts in the allocation of funds necessary or desirable. In addition, although we have no present plans or intentions, as strategic opportunities arise, we may use a portion of the proceeds of this offering to fund acquisitions, licensing and other strategic alliances.

A substantial portion of the net proceeds will be reserved for general corporate purposes. Our management will have broad discretion in the application of this portion of the net proceeds.

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Pending such uses, we intend to invest the net proceeds in direct and guaranteed obligations of the United States, interest-bearing, investment-grade instruments or certificates of deposit.

#### **DILUTION**

Our net tangible book value at July 31, 2004 was approximately \$2,733,000 or \$.68 per share of common stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the number of shares of common stock outstanding at that date. After giving effect to the sale of our common stock at an assumed initial public offering price of \$5.50 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at July 31, 2004 would have been approximately \$10,073,000, or \$1.80 per share (\$11,221,000 or \$1.92 per share assuming exercise of the underwriter's over-allotment option) of common stock. This represents an immediate increase in the net tangible book value of \$1.12 per share (\$1.24 per share assuming exercise of the underwriter's over-allotment option) to existing stockholders and an immediate dilution of \$3.70 per share (\$3.58 per share assuming exercise of the underwriter's over-allotment option) to new investors purchasing shares of our common stock in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share (1)		\$ 5.50
Net tangible book value per share at July 31, 2004	\$ .68	
Increase per share attributable to new investors	\$ 1.12	
As adjusted net tangible book value per share after the offering(2)		\$ 1.80
Dilution per share to new investors		\$ 3.70

Fair Value at December 31, 2015					
Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
\$ 49,321	\$	\$	\$14,950	\$	\$
	21,791				
	35,871				
	39,500			20,000	
	62,557			28,924	
	217,645			137,213	
\$ 49,321	\$ 377,364	\$	\$14,950	\$186,137	\$
\$	\$ 317,021	\$	\$	\$	\$
	2015 Level 1 \$ 49,321 \$ 49,321	2015 Level 1 Level 2  \$ 49,321 \$	2015 Level 1 Level 2 Level 3  \$ 49,321 \$ \$ \$ 21,791	2015 Level 1 Level 2 Level 3 Level 1  \$ 49,321 \$ \$ \$14,950  21,791  35,871  39,500 62,557 217,645  \$ 49,321 \$ \$377,364 \$ \$14,950	2015 Level 1 Level 2 Level 2  \$ 49,321 \$ \$ \$14,950 \$ 21,791 35,871 39,500 62,557 217,645 217,645 \$ 49,321 \$ 377,364 \$ \$14,950 \$186,137

Fixed-income investments categorized as Level 2 are valued at the custodian bank by a third-party pricing vendor's valuation models that use verifiable observable market data, e.g., interest rates and yield curves observable at commonly quoted intervals and credit spreads, bids provided by brokers or dealers or quoted prices of securities with similar characteristics. Pricing of the Company's Notes (See Note 7) has been estimated using other observable inputs, including the price of the Company's common stock, implied volatility, interest rates and credit spreads among others. Over time, the Company expects a market for the Notes to develop. At that time, the Company intends to use trade data as the principal basis for measuring fair value.

During the three months ended March 31, 2016, the Company did not have any transfers between levels.

The amounts in the Company's consolidated balance sheet for accounts receivable and accounts payable approximate fair value due to their short-term nature. Based on borrowing rates available to the Company, the fair value of capital lease and notes payable approximates their carrying value. The Company's milestone payment due to Wyeth (See Note 11) approximates its fair value at March 31, 2016, as the liability has been calculated based on an anticipated future payment date discounted at borrowing rates available to the Company.

### **Note 5 – Marketable Securities**

Marketable securities classified as available-for-sale as of March 31, 2016 and December 31, 2015 were comprised of (in thousands):

	March 31,	2016			December	31, 2015		
	Amortized Cost	l Gross Unrealiz Gains	Gross ædUnreali Losses	Fair zed Value	Amortized Cost	Gross Unrealiz Gains	Gross eUnrealize Losses	Fair ed Value
U.S. Treasury securities	\$21,779	\$ 12	\$ —	\$21,791	\$—	\$ —	\$ —	<b>\$</b> —
Debt securities of U.S. government agencies	25,869	8	_	25,877	_	_	_	_
Asset-backed securities	62,555	8	(6	) 62,557	20,748		(9)	20,739
Corporate debt securities	191,143	279	(5	) 191,417	116,821	29	(41)	116,809
Total	\$301,346	\$ 307	\$ (11	) \$301,642	\$137,569	\$ 29	\$ (50)	\$137,548

#### Marketable Securities - Unrealized Losses

The primary objective of the Company's investment policy is the preservation of capital; thus, the Company's investment policy limits investments to certain types of instruments with high-grade credit ratings, places restrictions on maturities and concentrations in certain industries and requires the Company to maintain a certain level of liquidity.

The Company owned 69 available-for-sale securities as of March 31, 2016. Of these 69 securities, 9 had combined unrealized losses of less than \$0.1 million as of March 31, 2016. The Company did not have any investments in a loss position for greater than 12 months as of March 31, 2016. The Company has evaluated its marketable securities and has determined that none of these investments has an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not more likely than not that the Company will be required to sell any securities with unrealized losses, given the Company's current and anticipated financial position.

## Note 6 – Goodwill and Other Intangible Assets

#### Goodwill

The change in the carrying amounts of goodwill for the three months ended March 31, 2016 was as follows (in thousands):

	Amount
Balance at December 31, 2015	\$53,065
Currency translation adjustments	701
Balance at March 31, 2016	\$53,766

## Identifiable Intangible Assets

Purchased intangible assets consisted of the following as of March 31, 2016 and December 31, 2015 (in thousands):

	March 31 Gross Carrying Amount	Accumulated	_	December Gross Carrying Amount	er 31, 2015 Accumulated Amortization	_
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$9,179	\$ (1,224	) \$ 7,955	\$8,858	\$ (1,070	) \$ 7,788
Collaboration agreements	4,145	(1,138	) 3,007	3,999	(994	) 3,005
Total identifiable intangible assets	\$13,324	\$ (2,362	) \$ 10,962	\$12,857	\$ (2,064	) \$ 10,793

Amortization expense for the three months ended March 31, 2016 and 2015 was \$0.2 million.

Estimated amortization expense for existing intangible assets for the remainder of 2016 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

Year	Amount
2016 (remainder)	\$ 664
2017	885
2018	885
2019	885
2020	756
2021	575

Note 7 – Long-Term Debt

#### Convertible Notes

In the first quarter of 2016, the Company issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the "Notes"). The Notes are senior unsecured debt obligations and were issued at par. The Notes were issued pursuant to an indenture dated January 29, 2016 (the "Indenture"),

between the Company and the trustee. The Company received \$315.0 million in net proceeds from the offering after deducting underwriting fees and offering expenses. The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company's common stock. The Notes are initially convertible into approximately 47,716,900 shares of the Company's stock based on the initial conversion rate of 146.8213 shares of the Company's common stock per \$1,000 principal amount of the Notes. This represents an initial conversion price of approximately \$6.81 per share of the Company's common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company's common stock of \$5.56 per share on January 25, 2016. In addition, the holders of the Notes may require the Company to repurchase the Notes at par value plus accrued and unpaid interest following the occurrence of a Fundamental Change (as described in the Indenture). If a holder of the Notes converts upon a Make-Whole Adjustment Event (as described in the Indenture), they may be eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 179.8561 shares per \$1,000 principal amount of Notes (subject to other adjustments as described in the Indenture).

The Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* and ASC 815-40, *Contracts in Entity's Own Equity*. Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon the Company's analysis, it was determined the Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt was recorded as a liability on the consolidated balance sheet.

In connection with the issuance of the Notes, the Company also paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represents a premium of approximately 75% based on the last reported sale price of our common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price of the capped call transactions. The Company evaluated the capped call transactions under ASC 815-10 and determined that it should be accounted for as a separate transaction and that the capped call transactions will be classified as an equity instrument.

The Company incurred approximately \$10.0 million of debt issuance costs during the first quarter of 2016 relating to the issuance of the Notes, which were recorded as a reduction to the Notes on the consolidated balance sheet. The \$10.0 million of debt issuance costs is being amortized and recognized as additional interest expense over the contractual term of the Notes of 7 years using the effective interest rate method. The Company also incurred \$0.9 million of expenses related to the capped call transactions, which were recorded as a reduction to additional paid-in-capital.

Total convertible notes payable consisted of the following at (in thousands):

	March 31, 2016	December 31, 2015
Principal amount of Notes	\$325,000	\$
Unamortized debt issuance costs	(9,729)	
Total convertible notes payable	\$315,271	\$

Interest expense incurred in connection with the Notes consisted of the following: (in thousands):

	Three Months Ended March 31,			
	2016	2015		
Coupon interest	\$ 2,099	\$		
Amortization of debt issuance costs	237			
Total interest expense on Notes	\$ 2,336	\$		

### Note 8 – Stockholders' Equity

During the first quarter of 2016, in connection with the Company's issuance of the Notes, the Company also entered into privately negotiated capped call transactions. The cost of the capped call transactions and associated expenses totaling \$38.5 million were recorded to additional paid-in-capital.

In March 2015, the Company completed a public offering of 27,758,620 shares of its common stock, including 3,620,689 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$7.25 per share resulting in proceeds, net of offering costs of \$11.6 million, of approximately \$190 million.

In 2012, the Company entered into an At Market Issuance Sales Agreement ("Sales Agreement"), under which the Company sold an aggregate of \$50 million in gross proceeds of its common stock. During 2015, the Company sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in \$14.6 million in net proceeds. The Sales Agreement was fully utilized at that time.

#### **Note 9 – Stock-Based Compensation**

#### Stock Options

The Amended and Restated 2005 Stock Incentive Plan ("2005 Plan") expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms. The Board adopted the 2015 Stock Incentive Plan ("2015 Plan") in March 2015, which was subsequently approved at the Company's annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees and consultants of and advisors to the Company and any present or future subsidiary. The 2015 Plan authorizes the issuance of up to 25,000,000 shares of common stock under equity awards granted under the plan. All such shares authorized for issuance under the 2015 Plan have been reserved. The Company will seek approval at its June 2016 annual meeting of stockholders to increase the number of shares of common stock available for issuance under the 2015 Plan by 6,000,000 shares. The 2015 Plan will expire on March 4, 2025.

The 2015 Plan permits and the 2005 Plan permitted the grant of stock options (including incentive stock options), restricted stock, stock appreciation rights, and restricted stock units. In addition, under the 2015 Plan, unrestricted stock, stock units and performance awards may be granted. Stock options and stock appreciation rights generally have

a maximum term of 10 years and may be or were granted with an exercise price that is no less than 100% of the fair market value of the Company's common stock at the time of grant. Grants of stock options are generally subject to vesting over periods ranging from six months to four years.

### Stock Options Awards

The following is a summary of option activity under the 2015 Plan and 2005 Plan for the three months ended March 31, 2016:

	2015 Plan			2005 Plan		
	Stock Options	Weighted- Average Exercise Price		Stock Options	Weighted- Average	
Outstanding at January 1, 2016	8,357,003	\$	8.97	15,450,542		xercise Price 3.31
Granted Granted	9,723,437	\$	4.99		\$	
Exercised	_	\$	_	(511,650)	\$	1.72
Canceled	(123,526)	\$	8.37	(136,875)	\$	4.48
Outstanding at March 31, 2016	17,956,914	\$	6.82	14,802,017	\$	3.35
Shares exercisable at March 31, 2016	1,916,292	\$	8.94	10,041,892	\$	2.79
Shares available for grant at March 31, 2016	6,998,086					

The fair value of stock options granted under the 2015 Plan and 2005 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	<b>Three Months Ended</b>			
	March 31,			
	2016	2015		
Weighted-average Black-Scholes fair value of stock options granted	\$2.45	\$2.92		
Risk-free interest rate	1.25%-1.70%	1.19%		
Dividend yield	0%	0%		
Volatility	57.86%-68.28%	53.58%-53.89%		
Expected term (in years)	4.26-7.28	4.26		
Expected forfeiture rate	0%-16.33%	16.33%		

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding under the 2015 Plan and 2005 Plan as of March 31, 2016 was approximately \$32.0 million and 8.3 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable under the 2015 Plan and 2005 Plan as of March 31, 2016 was approximately \$25.6 million and 6.7 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2016. This amount is subject to change based on changes to the closing price of the Company's common stock. The

aggregate intrinsic value of options exercised and vesting of restricted stock awards for the three months ended March 31, 2016 and 2015 was \$1.8 million and \$3.8 million, respectively.

#### Employee Stock Purchase Plan

In April 2013, the Company adopted an Employee Stock Purchase Plan (the "ESPP"), which authorized an aggregate of 2,000,000 shares of common stock to be purchased, which will increase 5% on each anniversary of its adoption up to a maximum of 3,000,000 shares. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At March 31, 2016, there were 821,846 shares available for issuance under the ESPP. The Company will seek approval at its June 2016 annual meeting of stockholders to increase the maximum number of shares of common stock available for issuance under the ESPP by 1,000,000 shares.

The ESPP is considered compensatory for financial reporting purposes. As such, the fair value of ESPP shares was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	2015
Range of Black-Scholes fair values of ESPP shares granted	\$1.86-\$3.38	\$1.06-\$2.24
Risk-free interest rate	0.22%-0.44%	0.05%-0.35%
Dividend yield	0%	0%
Volatility	46.14%-86.75%	40.79%-64.24%
Expected term (in years)	0.5-2.0	0.5-2.0
Expected forfeiture rate	5%	5%

### Restricted Stock Awards

The following is a summary of restricted stock awards activity for the three months ended March 31, 2016:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding and Unvested at January 1, 2016	25,000	\$ 8.72
Restricted stock granted	45,000	\$ 4.99
Restricted stock vested		\$
Restricted stock forfeited	(25,000)	\$ 8.72
Outstanding and Unvested at March 31, 2016	45,000	\$ 4.99

The Company recorded all stock-based compensation expense in the consolidated statements of operations as follows (in thousands):

	<b>Three Months Ended</b>		
	March 31,		
	2016	2015	
Research and development	\$ 3,233	\$ 1,032	
General and administrative	1,728	900	
Total stock-based compensation expense	\$ 4,961	\$ 1,932	

As of March 31, 2016, there was approximately \$53.1 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested stock options, ESPP and restricted stock awards. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.8 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 10 – U.S. Government Agreement, Collaboration and Joint Venture

#### HHS BARDA Contract for Recombinant Influenza Vaccines

HHS BARDA initially awarded the Company a contract in 2011, which funds the development of both the Company's quadrivalent seasonal and pandemic influenza virus-like particle ("VLP") vaccine candidates. The contract with HHS BARDA is a cost-plus-fixed-fee contract, which reimburses the Company for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of its multivalent seasonal and monovalent pandemic H7N9 influenza VLP vaccine candidates, In September 2014, HHS BARDA exercised and initiated a two-year option to the contract, which included scope to support development activities leading up to planned Phase 3 clinical studies, added \$70 million of funding on top of the remainder of the \$97 million base period funding, and extended the contract until September 2016. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the three months ended June 30, 2015. During the three months ended March 31, 2016, the Company recognized revenue of \$1.9 million, and has recognized approximately \$113 million in revenue since the inception of the contract. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. These indirect rates are subject to audit by HHS BARDA on an annual basis. An audit of fiscal years 2013 and 2014 has been initiated, but has not been completed as of the date of this filing. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustments are known and collection is probable.

#### Bill & Melinda Gates Foundation ("BMGF") Grant Agreement

In support of the Company's development of its respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate ("RSV F Vaccine") for infants via maternal immunization, in September 2015, the Company entered into an agreement ("Grant Agreement") with BMGF, under which it was awarded a grant totaling up to \$89.1 million (the "Grant"). The Grant will support development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and WHO prequalification of the RSV F Vaccine. The Company concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries. Unless earlier terminated by BMGF, the GACA will continue in effect until the latter of 15 years from its effective date, or 10 years after the first sale of a product under defined circumstances. The term of the GACA may be extended in certain circumstances, by a period of up to five additional years. Payments received under the Grant Agreement are being recognized in the period in which the research and development activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research and

development activities are performed. Cash payments received under the Grant are restricted as to their use until expenditures contemplated in the Grant are incurred. During the three months ended March 31, 2016, the Company recognized revenue of \$1.6 million, and has recognized approximately \$3 million in revenue since the inception of the contract. At March 31, 2016, the Company's current restricted cash and deferred revenue balances on the consolidated balance sheet represent its estimate of costs to be reimbursed and revenue to be recognized, respectively, in the next twelve months under the Grant Agreement.

#### **CPLB** Joint Venture

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited ("Cadila") named CPL Biologicals Private Limited ("CPLB") to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by the Company and 80% by Cadila. The Company accounts for its investment in CPLB using the equity method. Because CPLB's activities and operations are controlled and funded by Cadila, the Company accounts for its investment using the equity method. Since the carrying value of the Company's initial investment was nominal and there is no guarantee or commitment to provide future funding, the Company has not recorded nor expects to record losses related to this investment in the foreseeable future.

# Note 11 - License agreement with Wyeth Holding Corporation

In 2007, the Company entered into an agreement to license certain rights from Wyeth Holdings Corporation (now Wyeth Holdings LLC), a subsidiary of Pfizer Inc. ("Wyeth"). The Wyeth license is a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The Wyeth license provides for the Company to make an upfront payment (previously made), ongoing annual license fees, sublicense payments, milestone payments on certain development and commercialization activities and royalties on any product sales. Except in certain circumstances in which the Company continuously markets multiple products in a country within the same vaccine program, the milestone payments are one-time only payments applicable to each related vaccine program. At present, the Company's seasonal influenza VLP vaccine program (including CPLB's seasonal influenza program) and its pandemic influenza VLP vaccine program are the only two programs to which the Wyeth license applies. The license may be terminated by Wyeth only for cause and may be terminated by the Company only after it has provided ninety (90) days' notice that the Company has absolutely and finally ceased activity, including through any affiliate or sublicense, related to the manufacturing, development, marketing or sale of products covered by the license. In September 2015, the Company entered into an amendment to the license agreement with Wyeth. Among other things, the amendment restructured the \$3 million milestone payment ("Milestone") owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, would be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017. The amendment also restructured the final milestone payment to apply to the initial seasonal influenza VLP vaccine candidate being developed outside India. Thus, the aggregate milestone payments for a seasonal influenza VLP vaccine candidate developed and commercialized was increased from \$14 million to up to \$15 million. In connection with the execution of the amendment, the Company agreed to pay a one-time only payment to Wyeth. The amendment also increased annual license maintenance fees associated with VLP vaccine candidates from \$0.2 million to \$0.3 million per year. Payments under the agreement to Wyeth as of March 31, 2016 aggregated \$7.3 million. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, in other non-current liabilities at March 31, 2016. The Milestone was recorded as a research and development expense in 2014.

#### Note 12 – Facility Leases

In May 2016, the Company signed a new lease for a facility of approximately 150,000 square feet located in Gaithersburg, Maryland with a term expiring in 2030, unless terminated early by the Company in 2026. The lease contains provisions for future rent increases and periods in which rent payments are reduced (abated). Also, the lease obligates the Company to pay building operating costs. Under the terms of the lease, the landlord shall provide the Company with a tenant improvement allowance of \$9.6 million. In addition, the Company extended its Rockville, Maryland lease with a term expiring in 2020, unless terminated early by the Company in 2019.

Future minimum rental commitments under non-cancelable leases are as follows (in thousands and including the new lease):

	Amount
<u>Year</u>	
2016 (remainder)	\$4,739
2017	6,677
2018	9,654
2019	9,794
2020	8,265
Thereafter	42,750
Total minimum lease payments	\$81,879

# **Note 13 – Related Party Transactions**

Dr. Rajiv Modi, a director of the Company, is also the managing director of Cadila. The Company and Cadila have formed a joint venture, CPLB (See Note 10). A subsidiary of Cadila owns 2.5 million shares of the Company's outstanding common stock as of March 31, 2016. The Company and Cadila have also entered into a master services agreement, pursuant to which Cadila or CPLB may perform certain research, development and manufacturing services for the Company. For the three months ended March 31, 2016, the Company has incurred \$0.3 million in expenses under the agreement. The amount the Company owed CPLB under the master services agreement at March 31, 2016 and December 31, 2015 was less than \$0.1 million and \$0.7 million, respectively.

# Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Any statements in the discussion below and elsewhere in this Quarterly Report, about expectations, beliefs, plans, objectives, assumptions or future events or performance of Novavax, Inc. ("Novavax", and together with its wholly owned subsidiary Novavax AB, the "Company," "we" or "us") are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements with respect to our capabilities, goals, expectations regarding future revenue and expense levels; potential market sizes and demand for our product candidates; the efficacy, safety and intended utilization of our product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the development of our preclinical product candidates; the conduct, timing and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; the expected timing and content of regulatory actions; reimbursement by the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA"); payments under our license with Wyeth Holdings LLC (formerly known as Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. ("Wyeth"); payments by the Bill & Melinda Gates Foundation ("BMGF"); our available cash resources and the availability of financing generally, plans regarding partnering activities, business development initiatives and the adoption of stock incentive plans and amendments thereto, and other factors referenced herein. You generally can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "would," "possible," "can," "estimate," "continue," "ongoing," "consider," "anticipate," "in "project," "expect," "should," "would," or "assume" or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in them. Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate or materially different than actual results.

Because the risk factors discussed in this Quarterly Report and identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and other risk factors of which we are not aware, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by or on behalf of us, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. We have included important factors in the cautionary statements included in this Quarterly Report, particularly those identified in Part II, Item 1A "Risk Factors," and in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. These and other risks may also be detailed and modified or updated in our reports and other documents filed with the Securities and Exchange Commission ("SEC") from time to time. You are encouraged to read these filings as they are made.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. Further, any forward-looking

statement speaks only as of the date on which it is made, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

#### Overview

We are a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine platform technology, we produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant proteins critical to disease pathogenesis. Our product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus ("RSV"), seasonal influenza, pandemic influenza and Ebola virus ("EBOV"). We have additional preclinical stage programs for a variety of infectious diseases.

We are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M<sup>TM</sup>, has been successfully tested in a Phase 1/2 clinical trial for our pandemic H7N9 influenza virus-like particle vaccine candidate, and in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. ("Genocea") has licensed rights to our Matrix technology and has conducted Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

# **Clinical Product Pipeline**

Our clinical product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with potential to provide increased protection. Our nanoparticle technology platform targets antigens with conserved epitopes essential for viral function. Unlike traditional vaccines that 'mimic' viruses and elicit naturally occurring immune responses to them, our nanoparticles are engineered to elicit differentiated immune responses, which may be more efficacious than naturally-occurring immunity. Our vaccine technology has the potential to be applied broadly to a wide variety of human infectious diseases.

A current summary of our significant research and development programs, along with the programs of our joint venture, CPLB, and status of the related products in development follows:

Program Development Stage Funding Collaborator

**Respiratory Syncytial Virus (RSV)** 

•Older Adults Phase 3

•Infants via Maternal Immunization Phase 3 BMGF

•**Pediatrics** Phase 1

Influenza

•Seasonal Quadrivalent Phase 2 HHS BARDA •Pandemic H7N9 Phase 2 HHS BARDA

**Combination (Influenza/RSV)** Preclinical **Ebola Virus (EBOV)** Phase 1

# **Respiratory Syncytial Virus (RSV)**

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate ("RSV F Vaccine") for three susceptible target populations: older adults (60 years of age and older), infants via maternal immunization and children six months to five years of age ("pediatrics"). We estimate RSV F Vaccine peak revenue potential of six to eight billion dollars worldwide. Currently there is no approved RSV vaccine available.

Repeat infection and lifelong susceptibility to RSV are common and we currently estimate the global cost burden of RSV in excess of \$88 billion. Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is effective in pre-term infants, it is not indicated for use in other populations. We made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the virus. The F-protein has a highly conserved amino acid sequence called antigenic site II, which we believe is an ideal vaccine target. Palivizumab, which also targets antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen and enhanced its immunogenicity by exposing antigenic site II. Novavax' RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. The RSV F Vaccine elicits palivizumab-competing antibodies at levels that we expect to confer protection. The Novavax RSV F Vaccine is the first RSV vaccine to demonstrate efficacy in a clinical trial and we are positioned to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>1,2</sup>

# RSV Older Adults Program

Burden of Disease

Adults 60 years of age and older are at increased risk for RSV disease due to age related declines in their immune systems. In this population, RSV is an important respiratory virus, distinct from influenza viruses, that is responsible for serious lower respiratory tract disease and may lead to hospitalization or even death. Additionally, RSV infection can lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. RSV infection occurs as a recurrent and predictable annual epidemic throughout the world. In the U.S., the incidence rate is 2.5 million infections per year, and RSV is increasingly recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.<sup>3,4</sup> Based on our analysis of published literature applied to 2014 population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65. Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease across all populations.

### Clinical Trial Update

In August 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 1,600 older adults. The clinical trial was designed to prospectively examine the incidence of all symptomatic respiratory illnesses associated with RSV infection, in community-living older adults who were treated with placebo. The trial also evaluated safety and immunogenicity of our RSV F Vaccine compared to placebo. Finally, the trial estimated the efficacy of our RSV F Vaccine in reducing the incidence of respiratory illness due to RSV. The trial was the first to demonstrate efficacy of an active RSV immunization in any clinical trial population. In the per protocol population, the clinical trial showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (41%)

and, in an *ad hoc* analysis, showed a decrease in RSV disease with any symptoms of lower respiratory tract infection (45%) in older adults. The clinical trial established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory track symptoms. Efficacy against more severe RSV illness, defined by the presence of multiple lower respiratory tract symptoms or signs associated with difficulty breathing, was 64% in ad hoc analyses.

We initiated a pivotal Phase 3 clinical trial, known as Resolve<sup>TM</sup>, of our RSV F Vaccine in older adults in November 2015, and in December 2015, we completed enrollment of 11,850 older adult subjects at 60 sites in the U.S. The primary objective of the clinical trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. We expect to provide top-line data from this clinical trial in the third quarter of 2016.

<sup>&</sup>lt;sup>1</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>&</sup>lt;sup>2</sup> WHO Acute Respiratory Infections September 2009 Update: http://apps.who.int/vaccine\_research/diseases/ari/en/index2.html

<sup>&</sup>lt;sup>3</sup> Falsey, A.R. et al. (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>&</sup>lt;sup>4</sup> Falsey, A.R. et al. (1995) JID.172:389-94

In October 2015, we completed enrollment of 1,330 older adults in our Phase 2 rollover clinical trial of our RSV F Vaccine in the older adults who had participated in the recently concluded prior Phase 2 clinical trial. This trial is designed to evaluate safety and immunogenicity in response to immunization with the RSV F Vaccine during a second RSV season. We expect to provide top-line data from this trial in the second half of 2016.

## RSV Infants via Maternal Immunization Program

Burden of Disease

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide.<sup>5</sup> In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under one year of age.<sup>6,7</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>8,9</sup>

Clinical Trial Update

In September 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 50 healthy pregnant women and their infants. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine in pregnant women in their third trimester, and assessed the transplacental transfer of maternal antibodies induced by the vaccine. The trial also examined the impact of maternal immunization on infant safety during the first year of life and RSV-specific antibody levels through the infants' first six months of life. Immunized women demonstrated a geometric mean 14-fold rise in anti-F IgG, 29-fold rise in palivizumab-competing antibodies and a 2.7 and 2.1-fold rise in microneutralization titers against RSV/A and RSV/B, respectively. In contrast, women who received placebo demonstrated no significant change in antibody levels. The infants' antibody levels at delivery averaged 90-100% of the mothers' levels, indicating efficient transplacental transfer of antibodies from mother to infant. The estimated half-lives of infant PCA, anti-F IgG, RSV/A and RSV/B microneutralizing antibodies, based on data through day 60, were 41, 30, 36 and 34 days, respectively.

We announced the initiation of a global pivotal Phase 3 clinical trial, known as Prepare<sup>TM</sup>, of the RSV F Vaccine in 5,000 to 8,255 healthy pregnant women in December 2015. The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against symptomatic RSV lower respiratory tract infection with hypoxemia in infants through the first 90 days of life. This Phase 3 trial utilizes a group sequential design and is expected to take between two and four years to complete. This trial is supported by a grant (the "Grant") of up to \$89.1 million from BMGF. The Grant will support development activities, product licensing efforts and WHO

prequalification of our RSV F Vaccine. We concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the grant agreement (the "Grant Agreement"). Under the terms of the GACA, we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

In November 2014, the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research ("FDA") granted Fast Track designation to our RSV F Vaccine for protection of infants via maternal immunization. Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is designed to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

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<sup>5</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555
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<sup>&</sup>lt;sup>6</sup> Hall, C.B. et al. (2013) Pediatrics; 132(2):E341-348

<sup>&</sup>lt;sup>7</sup> Oxford Vaccine Group: http://www.ovg.ox.ac.uk/rsv

<sup>&</sup>lt;sup>8</sup> Glezen, W.P. et al. (1986) Am J Dis Child; 140:543-546

<sup>&</sup>lt;sup>9</sup> Glenn, G.M. et al. (2016) JID; 213(3):411-12

# RSV Pediatrics Program

Burden of Disease

There are currently approximately 18 million children in the U.S. between six months and five years of age. <sup>10</sup> In the U.S., RSV is responsible for approximately 57,000 hospitalizations of children under five years of age annually, the vast majority of which occur in infants less than one year old, and especially those under six months of age. <sup>11,12,13,14,15</sup>

Clinical Trial Update

In September 2015, we announced positive top-line data from a Phase 1 clinical trial of our RSV F Vaccine in healthy children between two and six years of age. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. Trial enrollment was concluded with a smaller than planned cohort so that dosing could be completed ahead of the 2014-15 RSV season. The vaccine was well-tolerated and serum samples collected from a subset of 18 immunized children in the per-protocol population, demonstrated that the RSV F Vaccine was highly immunogenic at all formulations and regimens. There were greater than 10-fold increases in both anti-F IgG and PCA antibody titers in the adjuvanted group and greater than 6-fold increases in anti-F IgG and PCA antibody titers in the unadjuvanted group. We are assessing the data from this clinical trial and in discussion with the regulatory agencies regarding the next steps in the development of our RSV F Vaccine for pediatrics.

#### Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as pediatrics and older adults, but also in the general population because of unique strains of influenza for which most humans have not developed protective antibodies. We are developing vaccine candidates for both seasonal and pandemic influenza. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately \$3.2 billion in the 2012/13 season to \$5.3 billion by the 2021/2022 season. 16

Traditional vaccine manufacturing methods utilize live influenza virus to infect eggs in order to produce trivalent seasonal influenza vaccine candidates. Our egg-free recombinant nanoparticle technology does not utilize either a live influenza virus or eggs, but rather a recombinant baculovirus and insect cells, which allows for the product to potentially be rapidly manufactured and quickly adapted to changing influenza strains. Further, we are developing a quadrivalent seasonal vaccine candidate, which we expect to elicit broader protection from circulating influenza strains. We are also exploring the development of novel influenza nanoparticle vaccine candidates. There are currently four quadrivalent seasonal influenza vaccines licensed in the U.S., although additional quadrivalent seasonal influenza vaccines are expected to be licensed over the next several years.

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<sup>10</sup> U.S. Census. www.census.go/population/international/data/idb/informationGateway.php
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<sup>&</sup>lt;sup>11</sup> Stockman, L.J. et al (2012) Pediatr Infect Dis J. 31: 5-9

<sup>&</sup>lt;sup>12</sup> CDC update May 5, 2015. http://www.cdc.gov/rsv/research/us-surveillance.html

<sup>&</sup>lt;sup>13</sup> Boyce, T.G. et al (2000) Pediatrics; 137: 865-870

<sup>&</sup>lt;sup>14</sup> Hall, C.B. et al (2009) NEJM; 360(6): 588-98

<sup>&</sup>lt;sup>15</sup> Hall, C.B. et al (2013) Pediatrics; 132(2): E341-8

<sup>&</sup>lt;sup>16</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

# Quadrivalent Seasonal Influenza Vaccine

Burden of Disease

The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention ("CDC") recommends that all persons aged six months and older be vaccinated annually against seasonal influenza. Influenza is a major burden on public health worldwide: an estimated one million deaths each year are attributed to influenza. It is further estimated that, each year, influenza attacks between 5% and 10% of adults and 20% to 30% of children, causing significant levels of illness, hospitalization and death. Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of vaccines can potentially be manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

# Clinical Trial Update

In July 2015, we reported positive data from our Phase 2 clinical trial of our quadrivalent seasonal influenza virus-like-particle ("VLP") vaccine candidate in 400 healthy adults that we initiated in November 2014. These data show that our quadrivalent seasonal influenza VLP vaccine candidate is well-tolerated, and can induce influenza antibody responses that met the immunogenicity targets. These results demonstrate the potential for our quadrivalent seasonal influenza VLP vaccine candidate to meet the FDA criteria for accelerated approval.

We were awarded a contract by HHS BARDA in 2011 to fund the development of both our quadrivalent seasonal influenza and pandemic influenza VLP vaccine candidates. This is a cost-plus-fixed-fee contract, which reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our vaccine candidates. We announced that HHS BARDA had exercised and initiated a two-year option to our contract in September 2014, which not only extended the expected term of the contract until September 2016, but also added scope to support our development activities leading up to planned Phase 3 clinical trials and \$70 million of funding on top of the remainder of the \$97 million base period funding. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the second quarter of 2015. During the three months ended March 31, 2016, we recognized revenue of \$1.9 million and have recognized approximately \$113 million in revenue since the inception of the contract. In recent meetings with HHS BARDA, we have been discussing the next steps in both our seasonal influenza VLP vaccine program and our pandemic influenza VLP vaccine program, as well as some of the delays associated with our development of both vaccine candidates. We have also discussed with HHS BARDA our preliminary efforts at developing influenza nanoparticle vaccine candidates. We expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development, although there can be

no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

# Pandemic H7N9 Influenza Vaccine

Burden of Disease

Prevention of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 influenza pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the next potential influenza pandemic are driving development of vaccines that can be manufactured quickly against a potentially threatening influenza strain. Industry and health experts have focused attention on developing a monovalent influenza vaccine against either the H5N1 strain or the H7N9 strain as potential key defenses against future pandemic disease threats.

<sup>&</sup>lt;sup>17</sup> Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>&</sup>lt;sup>18</sup> WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76

#### Clinical Trial Update

We have developed and delivered compelling safety and immunogenicity data on two pandemic vaccine candidates, H5N1 and H7N9. In September 2014, we announced positive results from a Phase 1/2 clinical trial of our H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 610 healthy adults. The Phase 1/2 clinical trial was designed as a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Our H7N9 influenza vaccine candidate, with and without Matrix-M, was highly immunogenic and well-tolerated. Matrix-M adjuvanted formulations demonstrated immunogenicity and dose-sparing benefits relative to unadjuvanted antigen. Hemagglutination-inhibiting antibody titers were comparable to those reported in prior clinical trials, and the vaccine elicited significant anti-neuraminidase antibodies. In October 2014, the FDA granted Fast Track designation to our H7N9 influenza vaccine candidate with Matrix-M.

Our pandemic influenza vaccine program is supported by our HHS BARDA contract. Like our seasonal influenza vaccine program, we expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development of our pandemic influenza vaccine candidate, although there can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

# **Combination Respiratory (Influenza and RSV)**

Given the ongoing development of our seasonal influenza vaccine candidate and our RSV F Vaccine, we see an important opportunity to develop a combination respiratory vaccine candidate. Early preclinical development efforts have given us confidence that such a combination vaccine is viable, and in animal models, provides acceptable immunogenicity. We expect to initiate a Phase 1 clinical trial of a combination respiratory vaccine in the first half of 2017.

# **Ebola Virus (EBOV)**

EBOV, formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans. Multiple strains of EBOV have been identified, the most recent of which, the Makona EBOV strain, is associated with a case fatality rate of 50% to 90%. <sup>19</sup> There are currently no licensed treatments proven to neutralize the virus, but a range of blood, immunological and drug therapies are under development. Despite the development of such therapies, current vaccine approaches target either a previous strain of the virus or were initially developed to be delivered by genetic vectors. In contrast, our EBOV glycoprotein vaccine candidate ("Ebola GP Vaccine") was developed using the Makona EBOV strain.

In July 2015, we announced data from our Phase 1 clinical trial of our Ebola GP Vaccine in ascending doses, with and without our Matrix-M adjuvant, in 230 healthy adults. Participants received either one or two intramuscular injections ranging from 6.5µg to 50µg of antigen, with or without adjuvant, or placebo. Immunogenicity was assessed at multiple time points, including days 28 and 35. These Phase 1 data demonstrated that our Ebola GP Vaccine is highly immunogenic, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, resulted in significant antigen dose-sparing. Although the adjuvanted Ebola GP Vaccine was highly immunogenic at all dose levels, the adjuvanted two-dose regimens induced Ebola anti-GP antibody geometric mean responses between 45,000 and 70,000 ELISA units, representing a 500 to 750-fold rise over baseline at day 35. In 2015, we also announced successful data from two separate non-human primate challenge studies of our Ebola GP Vaccine in which, in both cases, the challenge was lethal for the control animal, whereas 100% of the immunized animals were protected.

<sup>19</sup> WHO. http://www.who.int/mediacentre/factsheets/fs103/en/

# **CPLB Programs (India)**

CPL Biologicals Private Limited ("CPLB"), our joint venture company with Cadila Pharmaceuticals Limited ("Cadila") in India, is actively developing a number of vaccine candidates that were genetically engineered by us. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a manufacturing facility in India for the production of vaccines.

# Seasonal Influenza

CPLB received marketing authorization, the Indian equivalent of approval of a Biologics License Application ("BLA"), for its recombinant trivalent seasonal VLP influenza vaccine in 2015. Because the market for seasonal influenza in India is limited and highly competitive, CPLB is currently evaluating its marketing strategy for this vaccine.

#### Rabies

CPLB successfully completed Stage II of its 2-stage Phase 1/2 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered. The objective was to select a dose and regimen for a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies and travelers to such locations, and as a post-exposure prophylaxis using fewer doses than the current standard of care. In October 2014, CPLB presented clinical results from Stage I of the Phase 1/2 clinical trial, demonstrating that the vaccine candidate was well-tolerated and vaccine recipients, at various doses levels and schedules, showed seroprotective antibody levels at day 14 that were sustained through day 180. CPLB is seeking permission to conduct a Phase 3 clinical trial, currently expected to initiate in 2016.

## **Discovery Programs**

Our vaccine platform technology provides an efficient system that has the potential to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. In conjunction with government and/or global health authorities, we believe we can address emerging disease threats with pandemic potential. In addition to our response to the H7N9 influenza strain, we have developed a vaccine candidate to Middle East respiratory syndrome ("MERS"), caused by a novel coronavirus first identified in 2012. MERS emerged as a disease threat in 2013, and is currently being monitored by global health agencies, with the WHO reporting significant confirmed cases of infection and deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus ("SARS"). Within weeks of obtaining the sequence of the

circulating MERS strain, we successfully produced a vaccine candidate designed to provide protection. This vaccine candidate is based on the major surface spike protein, which we had previously identified as the antigen of choice in our work with a SARS vaccine candidate. In 2014, in collaboration with the University of Maryland, School of Medicine, we published results that showed our investigational vaccine candidates against both MERS and SARS blocked infection in laboratory studies. Although the development of a MERS vaccine candidate currently remains a preclinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities. We continue to pursue funding opportunities to move these programs into the next steps of development.

#### **Convertible Senior Notes**

In the first quarter of 2016, we issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the "Notes"). The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company's common stock. The initial conversion rate for the Notes is 146.8213 shares of the Company's common stock per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$6.81 per share of the Company's common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company's common stock of \$5.56 per share on January 25, 2016.

In connection with the issuance of the Notes, we paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represents a premium of approximately 75% based on the last reported sale price of our common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price of the capped call transactions.

#### Sales of Common Stock

In March 2015, we completed a public offering of 27,758,620 shares of our common stock, including 3,620,689 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$7.25 per share resulting in net proceeds of approximately \$190 million.

In 2012, we entered into an At Market Issuance Sales Agreement ("Sales Agreement"), under which we sold an aggregate of \$50 million in gross proceeds of our common stock. During 2015, we sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in approximately \$15 million in net proceeds. The Sales Agreement was fully utilized at that time.

#### Critical Accounting Policies and Use of Estimates

There are no material changes to our critical accounting policies as described in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the SEC.

### Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02") that increases transparency and comparability among organizations by requiring the recognition of lease

assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for us, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. We are currently evaluating when we will adopt the standard and the expected impact to our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* ("ASU 2016-09") that simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard will be effective January 1, 2017 for us, with early adoption permitted. We are currently evaluating when we will adopt the standard and the expected impact to our consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. In July 2015, the FASB approved a one-year deferral of the effective date of the new standard to 2018 for public companies, with an option that would permit companies to adopt the new standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. We are evaluating the potential impact that ASU 2014-09 will have on our consolidated financial position and results of operations.

#### **Results of Operations**

The following is a discussion of the historical financial condition and results of operations of the Company and should be read in conjunction with the financial statements and notes thereto set forth in this Quarterly Report.

Three Months Ended March 31, 2016 and 2015 (amounts in tables are presented in thousands, except per share information)

#### **Revenue:**

-

**Three Months Ended** 

March 31,

Change

2016 2015 **2015 to** 

<u>2016</u>

Revenue:

Total revenue \$4,218 \$9,877 \$(5,659)

Revenue for the three months ended March 31, 2016 was \$4.2 million as compared to \$9.9 million for the same period in 2015, a decrease of \$5.7 million or 57%. Revenue for the three months ended March 31, 2016 and 2015 is primarily comprised of services performed under the HHS BARDA contract, and to a lesser extent, the Grant Agreement. The decrease in revenue under the HHS BARDA contract of \$7.3 million is primarily due to a lower level of activity in the three months ended March 31, 2016 as compared to the same period in 2015, which also included revenue of \$3.1 million associated with our quadrivalent seasonal influenza VLP vaccine ("205 Trial"). This decrease in revenue was partially offset by \$1.6 million in revenue recorded under the Grant Agreement relating to our ongoing RSV F Vaccine Phase 3 clinical trial for the protection of infants via maternal immunization (Prepare).

For 2016, we expect our revenue, relative to 2015, to be driven by the outcome of our ongoing discussions with HHS BARDA relating to the next steps in the development of our quadrivalent seasonal and pandemic influenza vaccine candidates. In addition, we expect revenue in 2016 under the Grant Agreement to be significantly higher than in 2015.

#### **Expenses:**

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#### **Three Months Ended**

# March 31, Change 2016 2015 2015 to 2016 2016 Expenses: \$68,952 \$28,347 \$40,605 General and administrative 10,528 5,843 4,685 Total expenses \$79,480 \$34,190 \$45,290

#### Research and Development Expenses

Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for our programs. In addition, indirect costs such as fringe benefits and overhead expenses, are also included in research and development expenses. Research and development expenses increased to \$69.0 million for the three months ended March 31, 2016 from \$28.3 million for the same period in 2015, an increase of \$40.6 million, or 143%. The increase in research and development expenses was primarily due to increased costs associated with the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, including increased non-cash stock-based compensation of \$2.2 million. For 2016, we expect a significant increase in research and development expenses primarily due to our ongoing RSV F Vaccine candidate clinical trials and employee-related and facility costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates.

#### Expenses by Functional Area

We track our research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. At March 31, 2016, we had 410 employees dedicated to our research and development programs versus 287 employees as of March 31, 2015. Historically, we did not account for internal research and development expenses by project, since our employees work time is spread across multiple programs, and our internal manufacturing clean-room facility produces multiple vaccine candidates.

The following summarizes our research and development expenses by functional area for the three months ended March 31 (in millions).

	2016	2015
Manufacturing	\$28.6	\$17.3
Vaccine Discovery	1.5	1.6
Clinical and Regulatory	38.9	9.4
Total research and development expenses	\$69.0	\$28.3

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical trial, primary and secondary endpoints and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including: the number of patients who participate in the clinical trials and the specific patient population; the number of sites included in the clinical trials; whether clinical trial locations are domestic, international or both; the time to enroll patients; the duration of treatment and follow-up; the safety and efficacy profile of the vaccine candidate; and the cost and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when, and to what extent, we will generate future cash flows from our research projects.

### General and Administrative Expenses

General and administrative expenses increased to \$10.5 million for the three months ended March 31, 2016 from \$5.8 million for the same period in 2015, an increase of \$4.7 million, or 80%. The increase was primarily due to higher employee-related costs, including increased non-cash stock-based compensation of \$0.8 million, and professional fees for pre-commercialization activities, as compared to the same period in 2015. At March 31, 2016, we had 55 employees dedicated to general and administrative functions versus 38 employees as of March 31, 2015. For 2016, we expect general and administrative expenses to continue to increase primarily due to increased employee costs and activities related to the anticipated commercialization of our RSV F Vaccine.

# **Other Income (Expense):**

-

# **Three Months Ended**

	March 31, 2016 2015		Change 2015 to
Other Income (Expense): Investment income Interest expense Other expense	(33)	(36) (142)	
Total other income (expense)	\$(1,990)	\$(57)	\$(1,933)

We had total other expense of \$2.0 million for the three months ended March 31, 2016 as compared to \$0.1 million for the same period in 2015. Our investment income increased in the three months ended March 31, 2016 as compared to the same period in 2015 due to higher cash, cash equivalents and marketable securities balances. Our interest expense increased due to the issuance of the Notes in the first quarter of 2016.

#### Net Loss:

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### **Three Months Ended**

### March 31,

2016 2015 Change 2015 to 2016

Net Loss:

 Net loss
 \$(77,252)
 \$(24,370)
 \$(52,882)

 Net loss per share
 \$(0.29)
 \$(0.10)
 \$(0.19)

 Weighted shares outstanding
 270,179
 241,223
 28,956

Net loss for the three months ended March 31, 2016 was \$77.3 million, or \$0.29 per share, as compared to \$24.4 million, or \$0.10 per share, for the same period in 2015, an increased net loss of \$52.9 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, as compared to the same period in 2015.

Weighted average shares outstanding for the three months ended March 31, 2016 increased by 12.0% as compared to the same period in 2015, primarily as a result of sales of our common stock in 2015.

# **Liquidity Matters and Capital Resources**

Our future capital requirements depend on numerous factors including, but not limited to, the commitments and progress of our research and development programs, the progress of preclinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccines and products in various stages of development, and we believe our operating expenses and capital requirements will fluctuate depending upon the timing of certain events, such as the scope, initiation, rate and progress of our preclinical studies and clinical trials and other research and development activities.

As of March 31, 2016, we had \$433.9 million in cash and cash equivalents and marketable securities as compared to \$230.7 million as of December 31, 2015. These amounts consisted of \$132.2 million in cash and cash equivalents and \$301.6 million in marketable securities as of March 31, 2016 as compared to \$93.1 million in cash and cash equivalents and \$137.5 million in marketable securities as of December 31, 2015.

The following table summarizes cash flows for the three months ended March 31, 2016 and 2015 (in thousands):

Three	Months	Ended

	March 31,			
	2016	2015	Change 2015 to 2016	5
Summary of Cash Flows:				
Net cash (used in) provided by:				
Operating activities	\$(69,831)	\$(30,490)	\$ (39,341	)
Investing activities	(169,440)	17,788	(187,228	)
Financing activities	278,351	195,496	82,855	
Effect on exchange rate on cash and cash equivalents	37	(79)	116	
Net increase (decrease) in cash and cash equivalents	39,117	182,715	(143,598	)
Cash and cash equivalents at beginning of period	93,108	32,335	60,773	
Cash and cash equivalents at end of period	\$132,225	\$215,050	\$ (82,825	)

Net cash used in operating activities increased to \$69.8 million for the three months ended March 31, 2016 as compared to \$30.5 million for the same period in 2015. The increase in cash usage was primarily due to increased costs relating to our RSV F Vaccine, higher employee-related costs and timing of vendor payments.

During the three months ended March 31, 2016 and 2015, our investing activities consisted of purchases and maturities of marketable securities and capital expenditures. During the first quarter of 2016, we primarily purchased marketable securities to increase our rate of return on our marketable securities relative to returns available to money market funds. Capital expenditures for the three months ended March 31, 2016 and 2015 were \$5.5 million and \$4.9 million, respectively. The increase in capital expenditures was primarily due to facility improvements and the purchase of laboratory equipment to support our maturing product portfolio. In 2016, we expect our level of capital expenditures to be significantly higher than our 2015 spending as we continue to invest in our core operational infrastructure. If we receive positive data from our ongoing RSV F Vaccine Phase 3 clinical trial in older adults (Resolve), expected in the third quarter of 2016, this may result in a significant increase in capital expenditures as we prepare for initial commercialization and plan ahead for the additional manufacturing capacity necessary to meet expected demand in the upcoming years.

Our financing activities consisted primarily of sales of our common stock, issuance of Notes and to a lesser extent, stock option exercises and purchases under our employee stock purchase plan. In the three months ended March 31, 2016, we received net proceeds of \$276.5 million through the issuance of our Notes and payments of capped call transactions (See Note 7). In the three months ended March 31, 2015, we received net proceeds of approximately \$190 million through our public offering at \$7.25 per share and approximately \$4 million through our Sales Agreement at an average sales price of \$8.94 per share.

In August 2015, we amended the lease for our new facility located in Gaithersburg, Maryland to increase the amount of space leased by us to now include the entire facility. Under the terms of the amended lease, the landlord shall provide us with a tenant improvement allowance of \$3.9 million. Through March 31, 2016, we were funded \$1.4 million under this tenant improvement allowance. In May 2016, we entered into a new lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord shall provide us with a tenant improvement allowance of \$9.6 million.

In 2007, we entered into an agreement to license certain rights from Wyeth. The Wyeth license is a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The Wyeth license provides for us to make an upfront payment (previously made), ongoing annual license fees, sublicense payments, milestone payments on certain development and commercialization activities and royalties on any product sales. Except in certain circumstances in which we continuously market multiple products in a country within the same vaccine program, the milestone payments are one-time only payments applicable to each related vaccine program. At present, our seasonal influenza VLP vaccine program (including CPLB's seasonal influenza program) and our pandemic influenza VLP vaccine program are the only two programs to which the Wyeth license applies. The license may be terminated by Wyeth only for cause and may be terminated by us only after we have provided ninety (90) days' notice that we have absolutely and finally ceased activity, including through any affiliate or sublicense, related to the manufacturing, development, marketing or sale of products covered by the license. In September 2015, we amended the license agreement with Wyeth. Among other things, the amendment restructured the \$3 million milestone payment ("Milestone") owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, shall be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017. The amendment also restructured the final milestone payment to apply to the initial seasonal influenza VLP vaccine candidate being developed outside India. Thus, the aggregate milestone payments for a seasonal influenza VLP vaccine candidate developed and commercialized was increased from \$14 million to up to \$15 million. In connection with the execution of the amendment, we agreed to pay a one-time only payment to Wyeth. The amendment also increased annual license maintenance fees associated with VLP vaccine candidates from \$0.2 million to \$0.3 million per year. Payments under the agreement to Wyeth as of March 31, 2016 aggregated \$7.3 million. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, in other non-current liabilities at March 31, 2016.

Based on our March 31, 2016 cash and cash equivalents and marketable securities balances, along with anticipated revenue under the contract with HHS BARDA and the grant agreement with BMGF and other resources, we believe we have adequate capital to fund our operating plans for a minimum of twelve months. Additional capital may be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions.

Any capital raised by an equity offering will likely be dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. We cannot provide any assurance that new financing will be available on commercially acceptable terms, if at all. We will continue to assess our capital resources, including our ability to obtain additional capital, to support our research and development programs, and as a result of such assessment, we may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, and/or downsize our organization, including our general and administrative infrastructure.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of March 31, 2016, we had cash and cash equivalents of \$132.2 million, marketable securities of \$301.6 million, all of which are short-term, and working capital of \$413.5 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of March 31, 2016, our investments were classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in investment income. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income. The specific identification method is used in computing realized gains and losses on the sale of our securities.

We are headquartered in the U.S. where we conduct the vast majority of our business activities. We have one foreign consolidated subsidiary, Novavax AB, which is located in Sweden. A 10% decline in the exchange rate between the U.S. dollar and Swedish Krona would result in a reduction of stockholders' equity of approximately \$3.1 million at March 31, 2016.

Our Notes have a fixed interest rate and we have no additional material debt and, as such, do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

# **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the assistance of our chief executive officer and chief financial officer, has reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of March 31, 2016. Management recognizes that any

controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving such control objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2016, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

## **Changes in Internal Control over Financial Reporting**

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended March 31, 2016, and has concluded that there was no change that occurred during the quarterly period ended March 31, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION

#### Item 1A. Risk Factors

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

#### **Item 5. Other Information**

On May 3, 2016, the Company entered into a new lease with IP9 1201 Clopper Road, LLC ("Landlord") for approximately 150,000 square feet of facility space located at 1201 Clopper Road, Gaithersburg, Maryland 20878 (the "Lease Agreement"). Under the Lease Agreement, following the rent abatement period discussed below, the annual rent for the premises will be approximately \$3.3 million with annual increases of 2.5%. Pursuant to the terms of the Lease Agreement, the Company will receive rental abatement for the premises through November 30, 2017. The Lease Agreement also obligates the Company to pay building operating costs and requires that the Landlord provide the Company with a tenant improvement allowance of \$9.6 million. The lease term extends to 2030, unless earlier terminated by the Company in 2026. The foregoing description is qualified in its entirety by the text of the Lease Agreement, which is filed herewith as Exhibit 10.4.

#### Item 6. Exhibits

- Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to 3.1 Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed August 10, 2015)
- Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed March 12, 2013)
- 10.1\* Third Amendment to Lease Agreement between BMR-9920 Belward Campus, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated February 29, 2016
- 10.2†\*Employment agreement between Novavax, Inc. and John A. Herrmann dated April 1, 2012
- 10.3†\*Employment agreement between Novavax, Inc. and John J. Trizzino dated March 3, 2014

- 10.4\* Lease Agreement between IP9 1201 Clopper Road, LLC and Novavax, Inc., dated May 3, 2016
- Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 31.2\* Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 32.1\* Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) the Consolidated Statements of Operations for the three-month periods ended March 31, 2016 and 2015, (iii) the Consolidated Statements of Comprehensive Loss for the three-month periods ended March 31, 2016 and 2015, (iv) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2016 and 2015, and (v) the Notes to Consolidated Financial Statements.

Indicates management contracts, compensatory plans, or arrangements.

<sup>\*</sup>Filed herewith.

### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

# **NOVAVAX, INC.**

Date: May 4, 2016 By:/s/ Stanley C. Erck

President and Chief Executive Officer and Director

(Principal Executive Officer)

Date: May 4, 2016 By:/s/ Barclay A. Phillips

Senior Vice President, Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)