



June 29, 2010

Novavax, Inc. (Nasdaq/NVAX)

BUY **Playing for the Big League**

Novavax has expertise and leadership in advanced vaccine technology

Vernon T. Bernardino
Senior Research Analyst
(212) 551-3601

vbernardino@dawsonjames.com

INVESTMENT HIGHLIGHTS

Crucell Announces RSV Vaccine Discovery Program Crucell N.V. (CRXL, Not Rated), last week announced the start of a discovery program to develop and commercialize a universal respiratory syncytial virus (RSV) vaccine. Although Crucell's program is early, the company already markets vaccine products that it distributes in more than 100 countries around the world. Thus, this announcement represented the potential entrant of a strong competitor.

RSV is a Large Market Opportunity The announcement further validates our view that an RSV vaccine targets a large market opportunity. RSV is the most important cause of viral lower respiratory tract illness in infants and children and is the number one cause of hospitalizations for children under one year of age. Current prevention is based on the administration of *Synagis*, which is marketed by AstraZeneca plc (AZN, Not Rated). *Synagis* had sales of \$618 MM in 2007 and \$1.1 BN in 2009. Therefore, an RSV vaccine targets a very lucrative opportunity.

Crucell's Approach to Creating a Vaccine Could Be a Difficult Undertaking We anticipate Crucell will use an antibody-based approach. Since the company's goal is to make a universal vaccine, we do not believe this will be an easy task. Although the RSV F protein (RSV-F) is accessible on the virus surface, as with influenza there are many RSV strains circulating. Thus, a universal vaccine will likely require developing a mixture of polyclonal antibodies that simultaneously target multiple distinct epitopes.

Novavax' Approach Could Expand the RSV Market The nature of Novavax' virus-like particle (VLP) vaccine holds the promise of inducing a broad set of immune responses including antibody and cell mediated immune responses. We believe Novavax' approach could create a robust RSV vaccine at a far lower cost and potential safety advantages that might support market expansion into vaccination of full-term infants and the elderly at high risk of infection. We look for an IND submission and the potential launch of a Phase I trial in 2H10.

NVAX – Influenza VLP Leading the Lineup We believe Novavax is poised to deliver clear shareholder value-creating milestones in the next 6-9 months. We look for the announcement of an HHS contract awarded to Novavax in 2H10 to be a key near-term driver of the stock. At current prices NVAX stock presents an attractive value. We set an 18-month price target of \$4.50 (35x 2014 EPS of \$0.25 discounted annually at 25%) and recommend buying the shares.

Current Price **\$2.22** (intraday)
Price Target **\$4.50**

Estimates	2008A	2009A	2010E	
1Q March	(\$0.13)	(\$0.12)	(\$0.11)	A
2Q June	(\$0.15)	(\$0.10)	(\$0.11)	E
3Q September	(\$0.12)	(\$0.08)	(\$0.10)	E
4Q December	(\$0.16)	(\$0.15)	\$0.10	E
FY EPS	(\$0.53)	(\$0.45)	(\$0.20)	E
Revenues (MM)	\$0.33	\$1.64	\$25.42	E

Stock Data	06/28/10
52-Week Range	\$1.92-\$7.79
Shares Outstanding (mil.)	100.5
Market Capitalization (mil.)	\$223.1
Enterprise Value (mil.)	\$197.7
Debt to Capital (3/10)	0.0%
Book Value/Share (3/10)	\$0.63
Price/Book	3.63
Average Trading Volume (3-Month)	1,318,850
Insider Ownership	13.7%
Institutional Ownership	30.9%
Short Interest (Millions)	12.1
Dividend / Yield	\$0.00/0.0%



Source: BigCharts.com
Price target and ratings changes over the past 3 yrs:
Initiated - June 15, 2010 - Buy - Price Target \$4.50

KEY POINTS

- **Crucell Announces Work on Universal RSV Vaccine** Dutch vaccine maker, Crucell N.V. (CRXL, Not Rated), last week announced the start of a discovery program to develop and commercialize a universal respiratory syncytial virus (RSV) vaccine as part of the company's existing strategic collaboration with Johnson & Johnson (JNJ, Not Rated). Crucell's universal vaccine will target the most common strains for the prevention of severe RSV infections in infants and the elderly. Recall in our recent initiation report (*Novavax Inc. – Ready for the Show, June 15, 2010*) that Novavax has an early-stage RSV vaccine development program. Although Crucell's program is also early, the company markets seven vaccine products, and in 2009 distributed >115 MM vaccine doses in more than 100 countries around the world. Thus, this announcement represented the potential entrant of a strong competitor.
- **RSV is the Last Frontier in Pediatric Diseases with No Vaccine** This announcement, in particular JNJ's participation, further validates our view that an RSV vaccine targets a large market opportunity as there currently is none available. RSV is the most important cause of viral lower respiratory tract illness in infants and children and is the number one cause of hospitalizations for children under one year of age. Current prevention in developed countries is based on the administration of an RSV-neutralizing antibody, *Synagis* (palivizumab), which is given to high-risk infants such as premature newborns. *Synagis*, which had sales of \$618 MM in 2007 and \$1.1 BN in 2009, is marketed by AstraZeneca plc (AZN, Not Rated) who acquired the therapeutic through its \$15.6 BN acquisition of MedImmune in April 2007. *Synagis*, however, does not offer complete protection to all recipients and is not effective in inhibiting RSV replication in the upper respiratory passages. In addition, treatment with *Synagis* can cost up to \$6,000 for five once-monthly treatments. Therefore, an RSV vaccine with effects that are superior to current treatments could be a very lucrative opportunity.
- **Crucell's Approach to Creating a Vaccine Could Be a Difficult Undertaking** Studies of monoclonal antibodies against the RSV F (fusion) show it protects against hospitalizations for severe RSV disease, thus, developing a monoclonal antibody (mAb) would be the simplest strategy as it would be the easiest to make and have a high degree of specificity. We anticipate Crucell will use an antibody-based approach to target the most commonly found RSV strains. Since the company's goal is to make a universal vaccine, we do not believe this will be an easy task. Although the RSV F protein (RSV-F) is accessible on the virus surface, as with influenza there are many RSV strains circulating. Thus, a universal vaccine will likely require developing a mixture of polyclonal antibodies that simultaneously target several multiple distinct epitopes (viral components that acts as an antigen).
- **Recent Evaluation of Safety and Recommendation Against Numax Highlights the Limits of RSV MABs** The safety and potential benefit of a second-generation antibody-based RSV therapeutic was recently evaluated by the FDA's Antiviral Drugs Advisory Committee (ADAC). Previous RSV vaccine development was hampered by observations in the 1960's, when infants immunized with alum-adsorbed formalin-inactivated RSV (FI-RSV) developed an enhanced form of disease after subsequent natural RSV infection. A large percentage of the infants had to be hospitalized and two of them died. As a result, RSV vaccines are reviewed with a heightened evaluation of safety. However, some infants are not adequately protected by *Synagis*. *Numax* (motavizumab), a humanized mAb that was derived from palivizumab by MedImmune, was designed with enhanced binding to the RSV F protein with the goal of reduced dosing. *Numax* was evaluated in large-scale clinical studies and demonstrated efficacy in reducing the disease burden of RSV in high-risk infant populations. The ADAC reviews new antiviral therapies and, although not always followed, its recommendations are critically considered by FDA reviewers. On June 3, 2010, the ADAC voted 14 to 3 against recommending licensing *Numax*, citing a higher number of allergic reactions (i.e., 3-6 fold greater skin rash) and, albeit a secondary endpoint, a lack of proof demonstrating that it confers a survival advantage over *Synagis*. A decision by FDA on its evaluation of the biologics license application (BLA) for *Numax* was scheduled for June 24, however, the agency reset the decision date to August 27, 2010. We do not anticipate the FDA will approve licensing of *Numax* as we believe the agency is basically being asked to review a therapeutic that is non-inferior to one that is efficacious and safe all the while has the potential for serious adverse reactions. We believe these issues likely highlight the limits of an antibody-based approach.
- **Novavax' Approach Could Create an RSV Vaccine that Expands the Market** Recall that Novavax is using its virus-like particle (VLP) technology to create its own proprietary RSV vaccine. The technology lends itself to the creation of VLPs which are comprised of numerous copies of one or more virus envelope proteins that self-assemble in native conformation. An RSV VLP vaccine would imitate RSV without its replication genetic material to elicit an immune response. The particle nature of Novavax' vaccine holds the promise of inducing a broad set of immune responses including antibody and cell mediated immune responses to prevent infection of the respiratory tract and attack respiratory cells that may already be infected with RSV. Recall also that Novavax' vaccine production system provides advantages over traditional vaccine production methods that potentially include higher yields, significantly lower capital expenditures on infrastructure, competitive cost of goods, and scalable production. We believe Novavax'

approach can create a robust RSV vaccine at a far lower cost and potential safety advantages that therefore might support an expansion of the market perhaps to vaccination of full-term infants and the elderly at high risk of infection.

- **Results with Novavax' Early RSV VLPs Further Demonstrate the Versatility of VLP Technology** We remind investors that in March 2007 Novavax announced entering into a worldwide exclusive agreement with the University of Massachusetts Medical School (UMMS) to license paramyxovirus VLP technology which, for little upfront investment, expanded and strengthened the company's ability to develop novel vaccines. After evaluating epitopes that could be targeted with this technology, in December 2008 Novavax and UMMS announced results with an early RSV VLP construct that induced strong antibody responses in mice. RSV was a logical target virus as it is a member of the paramyxovirus family. In January 2010, the company announced positive preclinical results with a recombinant RSV-F particle vaccine in cotton rats, an animal model generally accepted as the best animal model that represents RSV infection and disease. Novavax was also able to successfully scale up cGMP manufacturing of RSV-F vaccine. The company is currently in preparation for an IND submission and the potential launch of a Phase I trial in 2H10.
- **Vaccine Forum Facilitates Presentation of Novavax' VLP Technology Before Key Opinion Leaders** We recently caught up with Novavax President and CEO, Rahul Singhvi, who participated in a roundtable discussion and made a presentation at the Facilitate Vaccine Forum, which was held June 21-23 in Barcelona, Spain. The Facilitate conferences bring together senior level industry and public sector figures that play central roles in driving the development of new prophylactic and therapeutic vaccines. We learned that the key takeaway from recent experiences by government health agencies in preparing for a pandemic that were discussed at the forum was the need to advance recombinant-based technologies to decrease the timeline of vaccine production in response to a newly emerged pandemic influenza strain. Dr. Singhvi's presentation updating the audience on novel influenza vaccine technologies and platforms, including VLP technology, was well received.
- **NVAX – Looking for HHS Award to be the Lead Off Driver** We believe Novavax is poised to deliver clear shareholder value-creating milestones in the next 6-9 months. We note that in April 2010 BARDA, a division of the U.S. Department of Health and Human Services (HHS), determined Novavax' proposal for the development of its VLP technology was in the competitive range for award of an advanced development contract. We look for the announcement of an HHS contract awarded to Novavax in 2H10 to be a key near-term driver of the stock. At current prices NVAX stock presents an attractive value, thus, we set an 18-month price target of \$4.50 and recommend buying the shares.

INVESTMENT SUMMARY

Novavax, Inc. (NASDAQ: NVAX) is a clinical-stage biotechnology company with expertise and leadership in advancing novel vaccine technology that overcomes what are normally high barriers to entry. Novavax employs proprietary technology to construct novel virus-like particle (VLP) vaccines against infectious diseases such as seasonal and pandemic influenza, herpes zoster, and respiratory syncytial virus. The company has announced robust pandemic and seasonal flu vaccine Phase II results that are competitive. Thus, Novavax is positioned to emerge as a major seasonal flu vaccine player. Mid-stage development biotech companies focused on therapies for infectious diseases currently trade at a mean enterprise value of \$391 MM. At a 48% discount compared to the mean enterprise value of comparable companies, we believe the company is undervalued (enterprise value \$202 MM). Our analysis derives a year-end 2011 fair value of \$4.50 (35x 2014 EPS of \$0.25 discounted annually at 25%) and a Buy rating for NVAX shares.

FIGURE 1: NOVAVAX, INC. – KEY MILESTONES

Date	Milestone
3Q10	- Submission of an IND to Evaluate RSV VLP Vaccine in a Phase I Clinical Trial
2H10	- Initiation of a Phase I Trial to Evaluate RSV VLP Vaccine
2H10	- Announcement of an HHS BARDA Contract Award for Development of Recombinant-Based Vaccine Technology
2H10	- Final Results of Phase II Trial of 2009 H1N1 Vaccine in Mexico
2011	- Initiation of a Phase IIb Confirmatory, Non-Inferiority Clinical Trial Evaluating Seasonal Flu Vaccine in the Elderly
2012	- Potential Submission of BLA for Seasonal Flu VLP Vaccine
2012	- Potential Licensing of Seasonal Flu VLP Vaccine

Source: Company reports and DJSI research.

INVESTMENT RISKS

The key risks are:

- Development Risk** Developing process, analytical and formulation methodology are necessary steps in the manufacturing process, as well as for supporting the intellectual property behind it. These steps are necessary to provide legal protection to maintain Novavax' position as the owner of this technology and to complete a file of documents that will be presented to regulatory authorities when Novavax files a Biologics License Application (BLA) for approval to market its VLP vaccine.
- Regulatory Risk** Novavax' vaccines are novel biologic entities using novel production methods. The company must still complete Phase III trials evaluating its seasonal flu vaccine prior to the licensure of the product and the methods to manufacture it.
- Commercialization Risk** Although Novavax' flu VLP vaccines appear competitive with traditional egg-based vaccines so far, the major vaccine manufacturers have a long presence in the market which may be difficult to overcome and achieve significant penetration of the market.
- Financial Risk** Capital resources are an issue. Novavax announced it had \$32.9 MM in cash which would not be enough to fund completion of clinical evaluation and commercialization of its seasonal flu vaccine. Our model assumes the company will need to raise \$30MM-\$55MM in capital each year through 2015 to fund clinical development and commercialization of its seasonal flu vaccine, as well as clinical development of its other vaccines.
- Market Risk** Although Novavax potentially offers flu vaccine supply in a shorter time frame, unless the immunogenicity observed with the company's flu VLP vaccine positively differentiates itself, future sales of Novavax' vaccines could slow dramatically as the supply of traditional vaccines enter the market.

FIGURE 2: NOVAVAX, INC. – QUARTERLY INCOME STATEMENT, 2009 – 2011E

	Fiscal year ends December 31		2010				FY 2010E	FY 2011E
	(all figures in \$000s except per share amounts)		Mar	Jun	Sept	Dec		
	FY 2008	FY 2009	1Q	2QE	3QE	4QE		
Product Revenues	\$ -	\$ 75	\$ -	\$ -	\$ -	\$ -	\$ 25,420	\$ 450
VLP Vaccines	-	-	-	-	-	-	-	-
Other Product Sales	-	-	-	-	-	-	-	-
Other Revenues	41	75	110	110	110	25,090	25,420	450
Total Revenue	70	75	110	110	110	25,090	25,420	450
Contract Research	41	75	110	110	110	25,090	25,420	450
Milestones	-	-	-	-	-	-	-	-
License Fees	-	-	-	-	-	-	-	-
Royalties & Other Revenue	29	-	-	-	-	-	-	-
Cost of Revenues	-	-	-	-	-	-	-	-
Gross Profit	70	75	110	110	110	25,090	25,420	450
R&D Expense	5,865	10,962	9,029	9,345	9,438	9,533	37,345	39,960
SG&A Expense	3,415	3,267	2,535	2,611	2,689	2,770	10,605	10,871
Total Operating Expenses	9,280	14,229	11,564	11,956	12,128	12,303	47,951	50,830
Income (Loss) from Cont. Operations Before Interest	(9,210)	(14,154)	(11,454)	(11,846)	(12,018)	12,787	(22,531)	(50,380)
Interest Income (Expense), net	(1,365)	43	42	21	5	24	92	149
Net Gain (Impairment) of Short-Term Investments	-	156	-	-	-	-	-	-
Income (Loss) from Continuing Operations	(10,575)	(13,955)	(11,412)	(11,825)	(12,013)	12,811	(22,439)	(50,231)
Income (Loss) from Discontinued Operations	(505)	-	-	-	-	-	-	-
Pro forma Net Income (Loss)	(10,575)	(13,955)	(11,412)	(11,825)	(12,013)	12,811	(22,439)	(50,231)
Net Income (Loss)	(11,080)	(13,955)	(11,412)	(11,825)	(12,013)	12,811	(22,439)	(50,231)
Shares Outstanding (000s)	68,144	95,984	100,188	103,945	117,843	122,262	111,060	127,725
Shares Outstanding (000s, Diluted)	68,144	95,984	100,188	104,132	118,055	122,482	111,214	127,955
EPS, Basic and Diluted	(\$0.15)	(\$0.15)	(\$0.11)	(\$0.11)	(\$0.10)	\$0.10	(\$0.20)	(\$0.39)

Source: Company reports, DJSI research.

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

Initiated – June 15, 2010 – Target \$4.50

Analyst Certification: The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Dawson James has not received investment banking compensation from the company mentioned in this report but may actively seek compensation for investment banking services in the future. Dawson James does not make a market in this security. Neither the research analyst whose name appears on this report nor any member of his household is an officer, director or advisory board member of the company. Dawson James did not receive any other compensation from the company in the previous 12 months. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future.

Ratings definitions: **1) Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; **2) Neutral:** the stock is fairly valued for the next 12-18 months; and **3) Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be sold.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Buy	10	67%	4	40%
Neutral	5	33%	4	80%
Sell	0	0%	0	0%
Total	15	100%	8	53%

DAWSON JAMES SECURITIES, INC., Member SIPC, FINRA, (the "Firm") does not make a market in these securities. The Firm may perform or seek to perform investment banking services for these companies in the future. Analysts receive no direct compensation in connection with the firm's investment banking business. All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report. The Firm, its officers, directors, analysts or employees may effect transactions in and have long or short positions in the securities (or options or warrants with respect thereto) mentioned herein. Although the statements of fact in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice. The Firm may effect transactions as principal or agent in the securities mentioned herein. The securities discussed or recommended in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

More detailed information concerning the rated companies referenced in this Note, including the full report, basis for price targets, risks and other disclosures, may be found at <http://www.DawsonJames.com/portal.html>.