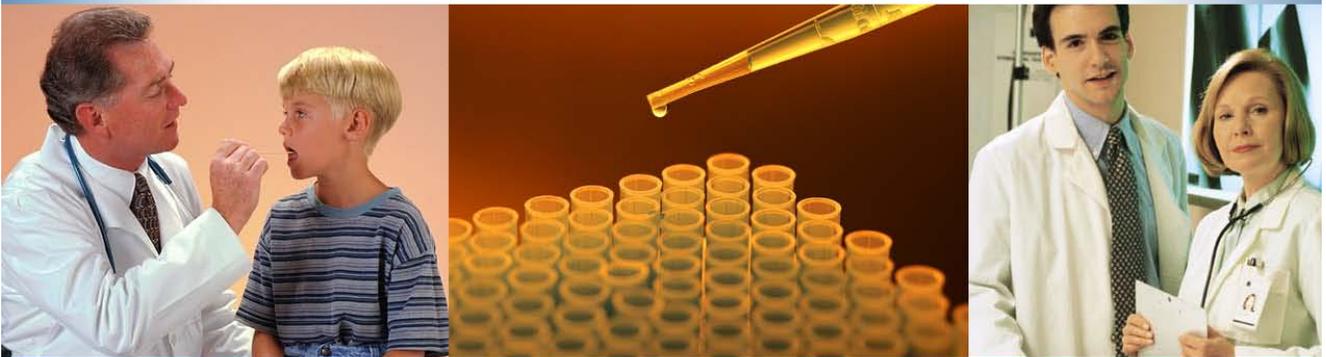


SPECIAL REPORT

# INVESTOR ESSENTIALS: PICKING WINNERS FOR PANDEMIC PROFITS



Actionable information for a flu-crazed market



## Investor Essentials: Picking Winners for Pandemic Profits

*Actionable Information for a Flu-Crazed Market*

In April of 2009 the identification of the H1N1 "swine flu" virus outbreak in Mexico grabbed headlines around the world and sent investors to a variety of volatile, small-cap vaccine stocks in hopes of striking gold amid pandemic hysteria. By June, when the World Health Organization (WHO) declared H1N1 an official pandemic, select biotech plays had already earned some investors a small fortune, multiplying several times from March lows. From there, the Swine Flu Stocks Index has pushed ahead rapidly, and thus far, those investors who gritted their teeth through volatility and pullbacks have been rewarded with continued, outsized gains.

As the northern hemisphere moves into the height of flu season, news flow around the pandemic is ramping up once again. On October 8, the Centers for Disease Control (CDC) said that it was seeing swine flu activity in 37 states, up from 27 states in the prior week. The CDC also noted delays in shipments amid high demand for both the seasonal flu vaccine and the H1N1 vaccine.

Meanwhile, the sector is in the midst of its largest pullback yet, and for investors looking to position their portfolios for flu season, there are more ways to trade the flu than ever. Risk averse investors have a handful of large-cap pharmaceutical plays to choose from, and various analysts have offered opinions on potential negative impacts on everything from travel stocks to restaurants. Meanwhile, some of the more volatile, small-cap names have proven the efficacy of their drugs. For others, it appears that trials are too far behind to capitalize on the current pandemic, but government funding and an otherwise strong pipeline could keep selected small-caps from crashing.

The following is an in depth analysis of the various participants in the vaccine and antiviral market, as well as some peripheral plays focusing directly on the impact of the current H1N1 swine flu pandemic. Whether managing a 401k, a complex leveraged arbitrage portfolio, or something in between, ample knowledge of the stocks poised to move in correlation to the virus can help to generate profits, and perhaps more importantly, protect against losses.

Included in this report are in depth looks at small-caps **Alpha Pro Tech (APT)**, **Sinovac Biotech (SVA)**, **Hemispherx Biopharma (HEB)**, **BioCryst Pharmaceuticals (BCRX)**, **Novavax (NVAX)**, **Generex Biotechnology (GNBT)**, **Dynavax (DVAX)**, and **Inovio Biomedical (INO)**; large-caps **GlaxoSmithKline (GSK)**, **Sanofi-Aventis (SNY)**, **Novartis (NVS)**, **Gilead Sciences (GILD)**, **Roche (RHHBY)**, **Astrazeneca (AZN)**, and **Baxter International (BAX)**, as well as a variety of other companies likely to be impacted by the swine flu pandemic.

## For Smaller Swine Flu Plays: Big Gains, Big Volatility, Big Risks

We begin with a look at micro- and small-cap names that have seen their stock prices rise and fall in tandem with the levels of swine flu hysteria in the media. Some of these companies show real promise. Others are fueled more by hype.

Overview					
Company	Ticker	Market Cap (in millions)	Revenue (trailing 12 months, in millions)	Alternative Business	H1N1 Application Status
Alpha Pro Tech	APT	155	43	good	Market Ready
Sinovac Biotech	SVA	318	48	good	Market Ready
Hemispherx Biopharma	HEB	226	<1	poor	Pre-Clinical
BioCryst Pharmaceuticals	BCRX	320	52	fair	Emergency Use
Novavax	NVAX	333	<1	fair	Clinical Stage
Generex Biotechnology	GNBT	140	1	good	Pre-Clinical
Dynavax Technologies	DVAX	68	56	good	Pre-Clinical
Inovio Biomedical	INO	154	4	fair	Pre-Clinical

Potential Volatility			
Company	Ticker	Short Interest *	Beta
Alpha Pro Tech	APT	0.6%	1.57
Sinovac Biotech	SVA	7.2%	2.80
Hemispherx Biopharma	HEB	12.0%	1.30
BioCryst Pharmaceuticals	BCRX	18.2%	3.03
Novavax	NVAX	16.7%	2.84
Generex Biotechnology	GNBT	1.0%	1.97
Dynavax Technologies	DVAX	1.7%	3.31
Inovio Biomedical	INO	1.5%	2.87

Many of the small-cap vaccine plays have been subject to significant price swings in relation to hype surrounding the H1N1 virus. A stock's **beta** coefficient is a standard measure of systematic risk in comparison to the market as a whole. A stock with a high **short interest** can be subject to a short-squeeze in the case of significant appreciation. This occurs when short sellers are forced to buy to cover their positions, therefore accelerating (and in some cases exaggerating) an existing rally.  
\*short interest as of 9/15

Burn Rate			
Company	Ticker	Cash and Short Term Investments (in thousands)	Burn Rate Rating
Alpha Pro Tech	APT	6,455	3
Sinovac Biotech	SVA	46,704	3
Hemispherx Biopharma	HEB	41,657	2
BioCryst Pharmaceuticals	BCRX	42,256	2
Novavax	NVAX	31,194	2
Generex Biotechnology	GNBT	1,061	1
Dynavax Technologies	DVAX	30,268	1
Inovio Biomedical	INO	24,258	2

The "**Burn Rate Rating**" is based on the company's average cash flow over the past four quarters and its current cash, equivalents, and short-term investments as most recently disclosed. Companies with positive cash flow averages for the past four quarters earned a **3**. Those with medium-term ability to continue operations at average quarterly burn rates received a **2**, and those with short-term cash concerns received a **1**.  
*Reuters* reported on October 7 that biotech firms have raised \$5.7 billion via debt and equity offerings this year, as vaccine hype lifted the demand for cash by 36%.

Overall Rating			<p>The <b>overall ratings</b> are not meant as "Buy," "Hold," or "Sell" recommendations, and should not be treated as such. The ratings are based on an overall assessment of the company's current exposure to the H1N1 market, the future impact of its current research and development related to the H1N1 threat, the strength of its other operating businesses, and the potential for downside risk relative to other small-cap stocks featured in this report.</p> <p><b>A rating of 3 is the most attractive while a rating of 1 is the least attractive</b></p>
Company	Ticker	Rating	
Alpha Pro Tech	APT	3	
Sinovac Biotech	SVA	3	
Hemispherx Biopharma	HEB	1	
BioCryst Pharmaceuticals	BCRX	3	
Novavax	NVAX	2	
Generex Biotechnology	GNBT	1	
Dynavax Technologies	DVAX	2	
Inovio Biomedical	INO	2	

A stock Index tracking both small- and large-cap plays is available at tickerspy.com. Visit [the tickerspy.com Swine Flu Stocks Index](http://tickerspy.com).

## Alpha Pro Tech Provides First Line of H1N1 Defense

Ontario, Canada-based **Alpha Pro Tech (AMEX: APT)** takes a somewhat alternative approach to swine flu prevention. While most of its small- and micro-cap peers are rushing to develop an H1N1 vaccine, Alpha Pro Tech is simply ramping up production of one of its existing products, the N-95 Particulate Respirator.

The N-95 respirator, so named for its ability to filter at least 95% of airborne particles, has been around for over a decade. Currently produced by a number of companies, including Cardinal Health (NYSE: CAH), Kimberly-Clark (NYSE: KMB), Medline Industries, and 3M (NYSE: MMM), N-95 respirators are the National Institute for Occupational Safety and Health- and CDC-recommended protective facemasks for medical workers exposed to infectious diseases.

As was the case during the SARS outbreak in 2003 and the Avian Flu outbreak of 2005 and 2006, medical groups like the CDC and WHO do not recommend the use of any type of mask against H1N1 except in cases of direct exposure, namely for individuals involved in the care of infected patients. Dick Thompson, a spokesman for the WHO, commented on the negative impact of public respirator use in a 2003 report from the *Associated Press*. "People buying them so they feel comfortable riding the subway doesn't make a lot of sense," said Thompson, who added, "We're just not going to encourage silliness because we don't want to see a shortage of masks." Still, images of mask-clad subway riders pollute the mainstream media, stirring up auxiliary demand for respirators.

Since the SARS epidemic of 2003, spikes in Alpha Pro Tech's stock have largely corresponded to times of significant viral outbreaks. While larger competitors are sharing the benefits of increased respirator demand, the wealth of other operating businesses at these companies mean respirator sales are little more than a rounding error. Alpha Pro Tech is thus the most pure U.S.-listed equity play on the N-95 respirator market.

Alpha Pro Tech's second-quarter net income jumped an astounding 463% in 2009 to \$2.2 million from \$385,000 in Q2 2008. While quadrupling profits is exciting, swine flu investors should pay closer attention to the company's profit margin. Thanks to increased sales in the high-margin Infection Control segment, Alpha's profit margin jumped from 4.3% in Q2 2008 to 14.9% in Q2 2009. The move points to the significance of N-95 respirators to Alpha Pro Tech's bottom line, though the sale of existing inventories in the building products division likely contributed as well.

On September 1, Alpha Pro Tech announced that it would triple N-95 respirator mask production during the fourth quarter. Company president, Al Millar said the additional output would be used to fulfill backorders, but excess capacity should be available for the upcoming flu season. The severity and breadth of the H1N1 outbreak at the height of this year's flu season will likely dictate whether the increased supply will be met by equal demand. If demand subsides following the fulfillment of backorders, excess inventory will likely be sold at a discount, limiting its benefit on the company's profits.

Over the last decade, spikes in Alpha Pro Tech's stock price have been followed by drops of almost equally impressive magnitude. In 2009 the stock has experienced only minor hiccups on its way from less than \$0.80 a share to a price of over \$6. Part of this run is attributable to a rebound of its building products division, which makes synthetic roof liners and house wraps applied during the construction process, so it is unlikely that the stock will return to its recent lows on an abating of swine flu fears alone.

Given the stock's dramatic run, however, it seems equally unlikely that it will sustain its current level for any duration of time after the hype surrounding swine flu subsides. Alpha Pro Tech is trading at a more than 60% premium to its value at any point during the real estate boom of 2001 to 2008. So while the company's building products division may cushion the fall from highs, it will likely be damaging nonetheless.

## China's Darling Is No One Trick Pony

Beijing-based vaccine company **Sinovac Biotech (AMEX: SVA)** has, like many of its peers, experienced its share of pops and drops riding waves of demand on the global epidemic rollercoaster.

In November of 2003, shortly after changing its name from Net Force Systems, Sinovac made its first run over \$6 on Chinese approval for human testing of its SARS vaccine. There was no shortage of publicity surrounding the announcement, and according to a 2003 report in *NewScientist*, some experts considered China's hasty approval of Sinovac's human trials unsafe. Despite millions of dollars in funding from China's government, and even a booster from the United States National Institute of Health, the SARS vaccine still isn't market ready.

Meanwhile, Sinovac's successful hepatitis A vaccine, Healive, did more than keep the lights on. Healive sales brought in \$577,000 in March of 2004 alone, more than double the prior year's monthly average. Fast-forward to 2009 and the vaccine is still a major contributor to Sinovac's

bottom line – in April the company sold \$12.8 million worth to the Chinese Ministry of Health. The company's Bilive hepatitis A and B vaccine was approved for marketing in 2005, and sold about a tenth as many doses as Healive in Q2 2009.

Separately, the Anflu split influenza vaccine has been in development since 2001, according to Sinovac's website. Late in 2005, the company received China's permission to test a potential avian flu inoculation, which Sinovac spokesperson Lu Zhenyou told *AFX News* could take at least a year to complete. Subsequent developments relating to the H5N1 vaccine sent shares soaring, but, as bird flu hype subsided, so did Anflu's impact on Sinovac stock. The vaccine quietly received China's approval for production in April 2008.

A year later, Sinovac announced the initiation of preparatory activities for a swine flu inoculation. On Friday, August 28, less than four months after the initial announcement, the Beijing Public Health Bureau announced that Sinovac would be one of four firms to supply 2.8 million of the city's citizens with seasonal flu immunizations. A few days later, the company announced that Chinese health regulators had approved its H1N1 vaccine for all individuals between three and sixty years of age – that's about a billion potential "customers." While Sinovac won't immunize the approved market in its entirety, a single dose is effective, meaning twice as many individuals may receive the vaccine as initially expected.

Sinovac's head start put it in a favorable position compared to some of its similarly volatile peers. However, while it was the first to announce that its vaccine was effective in a single dose, it would not be the last. In the weeks following Sinovac's announcement, pharmaceutical giants Novartis (NYSE: NVS) and GlaxoSmithKline (NYSE: GSK) also reported that a single dose of their respective H1N1 vaccines is sufficient as well.

Quick action following the initial H1N1 outbreak helped Sinovac prove the efficacy of its vaccine early and subsequently earned millions of orders from the Chinese government. On September 30, the company announced that China ordered an additional 3 million doses of its H1N1 vaccine, bringing its total order to 6.3 million. In the same press release, Sinovac said it expects the delivery of 4.5 million doses by the end of October.

Meanwhile, even if swine flu hype subsides prematurely, the company has a number of other promising ventures to keep its stock afloat. While a significant decline should be expected when the H1N1 virus is behind us, a -66% freefall from highs -- which the company has endured three times in the last decade – is unlikely. Sinovac's hepatitis vaccines have showed promise and profitability, and according to International Business Manager Helen Yang, there is more where that came from. Ms. Yang concluded her portion of the Sinovac's Q2 2009 earnings conference call with the following remarks:

Overall, we remain very excited about our growth prospects for 2009 and beyond. We have a robust pipeline of other vaccines, in addition to H1N1 vaccine including EV 71, a pneumococcal conjugated vaccine. Our objective for the next three to five years is to have one or two product candidates per year enter into clinical trials beginning in 2010 and one

or two products launched into the market per year commencing in 2012. In addition to our organic growth strategy, we have the financial flexibility to selectively pursue acquisition candidates that will help to expand our product pipeline.

This outlook is no doubt optimistic, but the company is surefooted, and capable of producing new products. There may be more opportunistic entry points in the next couple years, but Sinovac has room to the upside, and should be considered a dangerous short.

## Is This Volatile Micro-Cap Taking a Free Ride on Swine Flu Hype?

Over the last decade, Philadelphia, Pennsylvania-based **Hemispherx Biopharma (AMEX: HEB)** has traded for anywhere between \$0.30 and \$18 a share, and after a review of its current position, we tend to believe its value is closer to the former. Over the last year, H1N1 hype helped the stock recover from near historic lows, but since then there has been little to encourage investors that another rally is on the way.

Since the late 1980s, a drug called Ampligen has been Hemispherx's go-to for any attention-grabbing, disease-related headlines – although it has yet to receive approval for any commercial application. After the terrorist attacks of September 11, 2001 stirred up biological warfare fears, Ampligen was suggested as a smallpox treatment. Two years later Hemispherx sought patents for Ampligen and another drug, Alferon N, for the potential treatment and prevention of SARS. It has also been tested for against HIV, Ebola, and is currently banking on FDA approval as a chronic fatigue syndrome (CFS) treatment. In 2007 the company announced that a study had shown Ampligen could be used in conjunction with popular flu treatments Tamiflu and Relenza, hence the knee-jerk buying-spree that took place when swine flu grabbed headlines earlier this year.

While Hemispherx claims studies showed that Ampligen enhances the effectiveness of Tamiflu against bird flu, it was never approved or commercialized. According to the company's website, the drug is still in preclinical testing for the H5N1 avian flu strain.

Meanwhile, a press release found on the Hemispherx website, dated June 12, states that the company's Japanese collaborative partner, Biken, plans to up its flu vaccine production capacity by five times. Hemispherx noted that Ampligen is an essential co-ingredient for the vaccine; however, Biken's supposed expansion won't be completed until 2013. With little other news on the topic, we hesitate to get excited about the prospect.

At a September 9 investor conference, Hemispherx Chairman and CEO William Carter touted the company's potential in the pandemic flu market, though he never mentioned any direct efforts in response to the H1N1 swine flu outbreak. Although various media sources have lumped Hemispherx in with the other vaccine-related, small-cap swine flu plays, it appears that it doesn't belong. Initial speculation that the company would benefit from the outbreak could be justified based on its past efforts to capitalize on similar scenarios, but now that vaccines are being

approved for mass production and distribution, and their efficiency is even better than expected, the slim chance Hemispherx had to profit from the pandemic is shrinking by the day.

As for the future of Ampligen as a CFS treatment, *TheStreet.com* editor Adam Feuerstein isn't optimistic, although in a May 28 article, he wrote, "I applaud Hemispherx's efforts to promote Ampligen and extend the suspense of the FDA review." Based on a Q&A exchange at the September Rodman & Renshaw Global Investor Conference, it seems that the company's sense of urgency isn't where it should be considering the importance of the drug to its future. When asked whether anyone at the company had called the FDA about the then three-month-late review, Carter admitted, "No, it's our belief that in the good space of time, the FDA will respond to us much like they do to all other companies."

Carter has earned himself a reputation as a snake oil salesman in some circles, according to a 2001 article found on *Wired.com*. Back in the '80's he went as far as to pitch Ampligen to Phillip Morris (NYSE: PM) as a healthy cigarette additive, protecting smokers from cancer and emphysema. Based on Ampligen's track record, and Carter's shaky reputation, a bet on Hemispherx is a risky one to say the least.

## A Proven Immune Booster Takes on the Reigning Influenza Champ

When it comes to flu treatment (not prevention) doctors and patients have few options. While historically Roche's (OTC: RHHBY) Tamiflu and GlaxoSmithKline's (NYSE: GSK) Relenza have dominated the market, small Alabama-based pharmaceutical company **BioCryst Pharmaceuticals (NASDAQ: BCRX)** is making a big splash with its Peramivir drug.

One of the key attributes of peramivir is that it is issued intravenously. While that eliminates the possibility of over-the-counter sales, it could boost the drug's chance of success should a large number of flu-stricken patients rush to hospitals for treatment. Meanwhile, Tamiflu's Achilles heel is that it only comes in pill form. According to coverage by the *Associated Press*, many sick people can't swallow pills, and illness can impede the body's capacity to absorb oral medications. Relenza is taken with an inhaler, though an IV form has been successfully tested in compassionate use.

Testing has shown that a single dose of BioCryst's peramivir is as effective as a five-day Tamiflu regimen, and with fewer adverse reactions, according to the *AP*. The day after these results were released, BioCryst announced three international marketing partners to assist with sales in Mexico, Brazil, China, and Israel.

The U.S. Department of Health & Human Services committed \$77.2 million to the development of peramivir in September, bringing the current total to just under \$180 million over the last five years. While late-stage clinical trials may not be completed for another two flu seasons (one if this season is as heavy as some forecasts), peramivir could be approved for emergency use in response to the H1N1 pandemic.

According to BioCryst president and CEO Jon Stonehouse's explanation at a September 16 investor conference, the FDA contacted BioCryst asking the company to prepare for an emergency outbreak in two ways. The first is a compassionate use program. "Basically the way that works is the doctor calls FDA, FDA calls us, we ship the drug from our facility in Birmingham, Alabama to the doctor and the doctor treats the patient," Stonehouse explained.

The FDA also asked BioCryst to provide it with information for a pre-emergency use authorization (EUA) review. Essentially, BioCryst is in ongoing talks with the FDA, CDC, and the Biomedical Advanced Research and Development Authority (BARDA) about the progress of peramivir testing, so if an emergency scenario presents itself, the FDA will have the necessary information to either authorize or neglect to authorize use of the drug on a broader basis. On September 21, the company announced an official request for proposal from HHS, which indicated that the government could order between 1,000 and 40,000 courses of peramivir for the treatment of critically ill patients. According to *TheStreet.com*, a U.S. order could bring in between \$300,000 and \$14 million, assuming each course sells for around \$350.

Before backing up the truck to load up on BioCryst shares, there are a few downside risks. First, if swine flu's spread is kept in check by vaccines or other agents of prevention, the likelihood of a broader emergency-use application would diminish. Additionally, BioCryst added a line to the disclaimer in its most recent press release, which explained even if orders for peramivir do come through, there is no guarantee that they will be profitable. While we agree with BioLogic analyst Kevin McNamara, who explained to institutional clients that the company could just be covering all its bases, the prospect could weigh on stock's near-term performance.

The company booked a profitable quarter in Q4 2008 with EPS of \$0.26, but that was largely the result of \$26.5 million in previously deferred revenue related to the termination of a partnership with Roche. The consensus estimate for the third quarter is -22 cents a share. A profitable quarter would be a surprise for BioCryst, and based on the stock's run higher, the long-term bar has been set pretty high.

## Nipping Future Pandemics in the Bud

Clinical stage biotechnology firm **Novavax (NASDAQ: NVAX)** uses proprietary virus-like particle (VLP) technology in the development of novel vaccines for use in a variety of applications. After hitting an all-time low in March, the stock has multiplied by more than eight times. Though its September peak at over \$7.50 a share doesn't match the avian flu-driven rally to more than \$8 in 2006, swine flu has sent the stock higher from recent lows on a percentage basis than any prior pandemic threat.

The value in Novavax's approach lies in its methodology. While most vaccines are produced using chicken eggs in a process more than half a century old, Novavax is pursuing alternative production techniques that might one day enable quicker response to extreme circumstances like pandemic influenza.

Michael Brush explained the company's process in a *CNN Money* article during the avian flu outbreak of 2005: "Its system extracts genes from a virus and then uses insect cell lines to rearrange those genes into forms that trigger immune systems against the virus." The company says that VLPs resemble the virus but lack the genetic material to replicate it.

On June 4, shares of Novavax rocketed higher by as much as 50% after the company announced a partnership with the National Institutes of Health (NIH) to jointly evaluate the company's H1N1 vaccine. According to a *Forbes.com* report, Novavax whipped up swine flu VLPs just three weeks after receiving the genetic sequence from the CDC. During the company's second-quarter conference call on August 7, president and CEO Rahul Singhvi boasted that a swine flu vaccine was ready less than 12 week after receiving the sequence.

On September 1, 2009, Novavax announced a successful mid-stage human trial, which found its seasonal flu inoculation effective against three strains, including the H1N1 pandemic swine flu. After shooting higher on the news, Novavax stock has endured its longest consolidation pattern since the swine flu rally began this spring.

Rodmen & Renshaw biotech analyst Ren Benjamin told *Reuters*, "the government is not going to stop funding the development of next-generation vaccines that could address this limitation of technology," referring to the traditional practice utilizing chicken eggs. Thus a long-term investment in Novavax could be justified despite years of revenue declines. However, investors are not advised to build a position at current, hype-inflated price levels.

Though the company has remained quite optimistic whenever addressing investors or the media, recent insider activity suggests otherwise. Five Novavax executives, including Singhvi, have sold shares since the first of July, all at prices under the \$3 mark.

## Diabetes Stock Rides the H1N1 Hype

**Generex Biotechnology (NASDAQ: GNBT)** is a Toronto, Canada-based company involved in the development and manufacture of a variety of spray-delivery medications. Currently Generex Oral-lyn, the company's flagship diabetes treatment, is present in some overseas markets including India, South America, and according to Generex's March 13 SEC Form 10-K, the company planned a launch in Lebanon. In the United States, Oral-lyn is in late-stage clinical trials, and is being used in compassionate circumstances. Other revenue-generating products include over-the-counter sprays targeting diabetes, obesity, acid reflux, energy and other applications.

The company's "Immunomedicines" vaccine division puts it in play as a swine flu stock, although at this point it seems like a pure-play on the hype with little likelihood of capitalizing from the current pandemic. According to the Generex website, the company's product pipeline includes seven vaccines at different stages of preclinical and clinical testing. The AE-AI pandemic flu vaccine is the subject of current hype surrounding the H1N1 virus.

Like Novavax, Generex's technology is aimed at breaking away from the current, decades-old vaccine production technique, which involves growing the virus in chicken eggs. Generex points to the cost-effectiveness of its methodology as a primary benefit.

In an interview with *Fox Business*, Generex chairman, president, and CEO Anna E. Gluskin explained that the company's synthetic vaccine platform uses a peptide arrangement to simulate the virus, rather than taking the time to grow it. Once this "snapshot" has been developed, it can be used to trigger human T-cells to combat the virus. Gluskin said the process is much quicker than traditional vaccine development, and it costs approximately one-tenth the amount. Additionally, by using a dummy virus to trigger the immune system, there is no chance of accidental infection, which can be a risk with egg-based vaccines.

According to a September 9 report from *Reuters*, Generex will apply with U.S. regulators to begin human testing in the fourth quarter. With the height of flu season approaching, and numerous late-stage vaccine trials underway, it seems unlikely that the Generex's technology will have any impact on the current pandemic threat.

Unlike some other long-shot swine flu plays, Generex is currently trading at a small fraction of its all-time highs at around \$20 a share. After dipping to below ten cents near the equity markets' bottom this spring, the stock still trades for less than a dollar.

An investment in Generex is a play on the near-term potential of its Oral-lyn diabetes treatment in the U.S. market and the long-term potential of its vaccine production process. There is no doubt that faster vaccine development with fractional costs would be a huge hit if safety and efficacy were on par with today's vaccines. However, it is far too soon to make more than a speculative play on these grounds alone.

## Hepatitis Play Shows Flu Potential

Berkeley, California-based **Dynavax Technologies Corporation (NASDAQ: DVAX)** earned its place in the Bird and Swine Flu Stocks Index with the development of a universal flu vaccine, funded in part by grants from the National Institutes of Health.

According to the company's website, Dynavax has established a global supply agreement with Swiss pharmaceutical giant Novartis' vaccines and diagnostics division. However, even if effective, it could be a long time before the vaccine hits the market.

During the Dynavax second-quarter earnings conference call on August 4, president and CEO Dino Dina explained that the vaccine had demonstrated effectiveness in pre-clinical testing, but the company had not yet moved into clinical trials. Dina said, "We have determined that it's ... ready to go into the clinic and we are currently reviewing our plans ... to advance in that direction."

Investors can look for further flu news from Dynavax down the road, but in the near term, its experimental hepatitis B vaccine will likely remain the stock's primary driver.

## Successful Ferret Trial Could Mean Big Things for Inovio

When **Inovio Biomedical (AMEX: INO)** announced the success of its H1N1 vaccine on mice and pigs at the end of July, the company's shares nearly quadrupled. The San Diego, California-based DNA vaccine company's value was cut in half the next day, however, as traders took quick profits. Several months later, and still left with a significant portion of its swine flu rally, investors are placing bets on the stock's next move.

On October 5, San Diego, California-based Inovio announced that a combination of its H1N1 vaccine candidates achieved protective antibody responses in 100% of ferrets used in testing. While racking up animal inoculations doesn't mean much at face value, the company explained, "The ferret model is widely considered to be the most representative of human influenza." The success of the trial is promising, but like many other small-cap vaccine plays, it could be a long time before it has any impact on the company's bottom line.

Inovio CEO Dr. J. Joseph Kim boasted, "The beauty of our approach is that we can design universal DNA vaccines with broad protective capabilities against known and unknown strains." However, the press release neglected to mention any plans of applying for FDA approval – perhaps why the company's stock slipped on the report.

An investor relations representative told *onemedplace.com* that Inovio could submit an Investigational New Drug application in the first half of 2010. While this would seem to be the logical next step for the vaccine, we'd hold off making any bets until a more official announcement is made.

If H1N1 panic continues to grow, Inovio shares could ride the hype higher. However, longer-term investors should be wary of potential pullbacks as the pre-clinical vaccine has a ways to go before reaching the market.

## Large Cap Pharma Firms do the Swine Flu Heavy Lifting

While small- and micro-cap swine flu plays have caught the fancy of many investors in 2009, several of the world's largest pharmaceutical companies are set to provide the bulk of the vaccines and treatments that will be in demand this flu season.

Market Exposure				
Company	Ticker	Vaccine	Antiviral	Mask
GlaxoSmithKline	GSK	x	x	x
Sanofi-Aventis	SNY	x		
Novartis	NVS	x		
Gilead Sciences	GILD		x	
Roche	RHHBY		x	
AstraZeneca	AZN	x		
Baxter International	BAX	x		

The large-cap stocks featured in this report are involved in different sectors of the H1N1 market. The three broad categories are **Vaccine**, which is preventative; **Antiviral**, which is a treatment, and **Mask**, which is an alternative, non-medical play on the preventative market.

Overall Rating		
Company	Ticker	Rating
GlaxoSmithKline	GSK	3
Sanofi-Aventis	SNY	3
Novartis	NVS	3
Gilead Sciences	GILD	2
Roche	RHHBY	1
AstraZeneca	AZN	3
Baxter International	BAX	2

The **overall ratings** are not meant as "Buy," "Hold," or "Sell" recommendations, and should not be treated as such. The rating signifies which stocks are set to see the most benefit from the H1N1 pandemic relative to their peers. All of the large-cap stocks in this report are currently valued at more than \$30B, and have significant other revenue-generating operations in a variety of segments of the pharmaceutical market.

**Stocks rated 3 are best positioned to benefit from the H1N1 pandemic while stocks rated 1 have the least to gain from it.**

A stock Index tracking both small- and large-cap plays is available at tickerspy.com. Visit [the tickerspy.com Swine Flu Stocks Index](http://tickerspy.com).

### GlaxoSmithKline

Weighing in at \$103 billion, U.K.-based **GlaxoSmithKline (NYSE: GSK)** is the second largest player in the Swine Flu Stocks Index. Offering a vaccine, a protective face respirator, and a popular influenza treatment, Glaxo has all the bases covered for any intensification of the H1N1 outbreak.

As of October 6, Glaxo had raked in 440 million vaccine orders, which could be worth \$3.5 billion, according to *Reuters*. While the vaccine was not named by the FDA on September 15, when four competitors saw their vaccines approved by the FDA, Glaxo's vaccine is expected to be approved by the FDA and the company is one of the five firms to receive vaccine orders from the U.S. Glaxo said in an August press release that it had "a variety of agreements in place with the U.S. Government to supply pandemic products worth \$250 million." Company representative Sarah

Alspach told *Bloomberg*, "We are working with the FDA and HHS to support the government's plans for vaccination in the U.S."

According to *Reuters*, Glaxo's vaccine uses a special adjuvant, an additive that makes the vaccine more effective, that may substantially reduce the amount of active ingredient required in each shot. The delays in Glaxo's vaccine being "officially" named as part of the U.S. supply may be a result of the FDA's preference for non-adjuvanted vaccines. Even if the U.S. ends up snubbing Glaxo's vaccine (though this appears unlikely), it won't represent a huge loss for the firm. *WebMD* reported that Glaxo is expected to supply less than 4% of U.S. swine flu vaccine in 2009, whereas the company has much larger exposure to Japan and other parts of the world. In Japan, Glaxo has been tapped to supply enough vaccine for 35 million people, an order worth about \$725 million. Novartis (NYSE: NVS) will supply the remainder of Japan's \$1.1 billion import order. The European Union has also backed vaccines from the two companies.

The prospect of a global vaccine shortage or delay bodes well for Glaxo's flu treatment Relenza, which is currently second in market share only to Roche's (OTC: RHHBY) Tamiflu. According to Glaxo's July 22 second-quarter earnings conference call, tendencies towards antiviral stockpiling have grown significantly since the last pandemic threat. Additionally, CEO Andrew Witty said he doesn't expect the sort of peak and trough demand experienced in the past. He explained, "we will have periods of extremely heightened demand as we're seeing now," but he also suggested that subsequent periods of "fairly sustained demand" should follow.

Witty also noted the increasing diversification of such stockpiles. "What we're seeing is very much a movement towards 75/25," he said, noting the ratio of Tamiflu to Relenza, "maybe not yet 60/40, but certainly two-thirds/one-third type of numbers." Fuzzy math aside, the company seems confident that its antiviral market share is on the rise ahead of an outbreak the WHO estimates could infect more than 2 billion people.

Glaxo also broke out its anticipated Relenza production figures during the July conference call, forecasting annual output more than triple prior estimates. "By the end of the year," explained Witty, "we'll be in a position to move into a capacity of around 190 million courses per year." Currently Relenza is only approved as an inhaler, but an intravenous form of the drug saved the life of a 22-year-old swine flu patient in London, according to *Reuters*.

Glaxo's third swine flu play is a protective facemask, which the company admitted it had only a small capacity to produce in during a conference call this summer. In July, Witty said that the way to commercialize the masks would be via a sizable manufacturing partner. With most mask companies already maxing out production of their own products, it is unlikely that this segment will have any significant impact on Glaxo's bottom line.

Overall, GlaxoSmithKline is a strong company with numerous popular and profitable drugs, and the capability to expand on its current lineup via acquisition or its own research and development. By some standards, the revenue generated from pandemic products is only a drop in the bucket

for the massive pharmaceutical company, but as long as demand is as strong as expected, exposure to the H1N1 market is a good perk for a strong play on the drug sector.

## Sanofi-Aventis

Sanofi Pasteur (SP), a subsidiary of French pharma giant **Sanofi-Aventis (NYSE: SNY)**, owns 40% of the seasonal influenza vaccine market – more than any other company, according to a report in *TheStar Online*. Additionally, the company's H1N1 vaccine was one of four approved by U.S. health regulators in mid-September.

Sanofi CEO Chris Viehbacher told *Le Figaro* newspaper that the U.S. should receive its first batch of vaccine by mid-October. According to *Reuters'* September 3 coverage of the report, Viehbacher "added that Sanofi could, in theory produce 800 million doses of its H1N1 flu vaccine per year."

The company boosted its full year 2009 EPS growth guidance to 10% over FY 2008 in July. Since Sanofi doesn't book sales until delivery is made, and the delivery schedule of H1N1 vaccine is uncertain, the company used only a conservative figure for the impact of the pandemic vaccine on this guidance. On September 24, CEO Viehbacher told *Reuters* the H1N1 vaccine should have a significant positive impact on revenue this year and next, noting, "It's a nice short-term boost for sales and cash flow."

As relates to a long-term investment, the delivery time, and subsequent sales booking of H1N1 vaccines shouldn't matter to investors. The orders have been placed, and all signs point to a global vaccine shortage. As of September 22, the U.S. alone had ordered 75.3 million doses from Sanofi. The improved cash flow should help to support ongoing R&D for other drugs, including the company's breakthrough experimental AIDS vaccine. Meanwhile blockbusters like blood-thinner Plavix and cancer treatment Taxotere should continue to bring in a consistent revenue stream.

## Novartis

Basel, Switzerland-based drugmaker **Novartis (NYSE: NVS)** tips the scales at \$115 billion. So while multimillion-dollar deals can send small-cap biotech stocks to the moon, it takes a more substantial development to shift Novartis.

On September 3, the Swiss pharmaceutical giant was the first large-cap vaccine producer to announce that a single dose was adequate in protecting against the H1N1 swine flu virus. Even before receiving FDA approval, the company scored a \$690 million order from the U.S., which was about evenly split between vaccine and adjuvant. While the FDA has never approved additives for flu vaccines, a CDC director told *Bloomberg* it could mean the difference between the swine flu inoculation working in one dose or two.

Should the supply be sufficient, adjuvant will likely be left aside, but in cases of shortage, the slight risk of excessive protection from the vaccines might be one worth taking. Novartis' MF59 adjuvant has been used in Europe and used by more than 40 million people in seasonal flu vaccines, according to *Bloomberg*.

Novartis' share of Japan's \$1.1 billion H1N1 vaccine import order will be about a third of GlaxoSmithKline's, according to a September 11 report by *Reuters*. The European Union announced that it backed both companies on September 25, though sales figures were not divulged.

While Novartis sold nearly ten times as much vaccine and adjuvant to the United States, Glaxo's dominance in Japan brings their respective likely vaccine sales totals for the two countries to \$970 million and \$890 million respectively. While sales totals from the rest of the world could skew the competitive balance in vaccines, Glaxo's exposure to the antiviral market makes it a one-two punch that will be difficult for similarly capitalized drug makers to counter.

However, if vaccines are effective around the world, and the demand for antivirals is weaker than expected, untapped stockpiles of Glaxo's Relenza will weigh on future demand. Should that be the case, Novartis is a more appealing large-cap play due to its singular preventative exposure.

## Gilead and Roche

There are two U.S.-listed plays on a swine flu-driven demand boost for the world's most popular flu medicine. Oseltamivir, or Tamiflu, as it is more commonly known, was initially developed by **Gilead Sciences (NASDAQ: GILD)** and is now sold by **Roche (OTC: RHHBY)**. Now the former receives royalty payments from the latter on sales of the popular antiviral.

Gilead's Tamiflu royalties vary from 14% to 22% of Roche's Tamiflu sales and are reported on a one-quarter lag. During the second quarter, Gilead reported that its royalties were 15% of total Tamiflu sales, or \$52 million. Roche doesn't typically break out its Tamiflu sales number, but working backwards from Gilead's Q2 royalty number, Roche saw about \$347 million in sales of the antiviral in Q1. On its Q2 conference call, Roche noted "some tailwinds" from Tamiflu, which means that Gilead's Tamiflu royalty payment for Q3 will likely be a healthy number.

At Gilead, the second quarter royalty payments represented 3.2% of total revenue. At Roche, estimated Tamiflu revenue represented around 3.4% of first quarter sales.

While Roche is ramping up production of the drug, there are some supply related-issues that could weigh on the impact of boosting output. In May, the *Financial Times* reported that Tamiflu was effective when taken up to two years beyond its supposed expiration date. While it is likely that demand will easily match supply of the drug in the short term, a longer shelf life could exaggerate the negative impact of a weaker-than-expected flu season and H1N1 threat. If Tamiflu stockpiles go unused, an extended expiration date would only further extend the oversupply.

Another downside to Tamiflu is that it can only be taken orally. As noted by the *Associated Press*, the seriously ill can have trouble swallowing pills. In some cases GlaxoSmithKline's Relenza, which is inhaled, faces similar issues, but unlike Tamiflu, an IV form of Relenza has been successful in compassionate use. New competition also comes from Alabama-based small-cap BioCryst pharmaceuticals, which produces an IV antiviral shown to be as effective as Tamiflu, but faster and with fewer negative reactions.

On September 23, *Barron's* noted that the recent \$47 billion acquisition of Genentech will be the primary driver of Roche's performance in the medium term. While we tend to agree, the additional cash flow from increased Tamiflu output will likely be put to good use.

Investors looking to bet on Tamiflu should go long Gilead rather than Roche -- Gilead doesn't bear the same marketing expenses on Tamiflu revenue that Roche does -- but we consider GlaxoSmithKline the best large-cap swine flu play due to its preventative and treatment exposure.

## AstraZeneca

\$64 billion, U.K.-based drug maker **AstraZeneca (NYSE: AZN)** first entered discussions with the CDC about producing a swine flu vaccine via its MedImmune subsidiary back in April. The result was one of the five vaccines chosen by the U.S. to fill its massive 195-million dose swine flu vaccine order.

AstraZeneca's 42 million-dose share of the U.S. market is worth \$453 million, according to a September 21 press release. During a July 30 conference call, CEO David Brennan speculated, "We may be able to produce up to 200 million doses of bulk vaccine to the H1N1 virus." Based on that assumption, and the proceeds from the 42 million-dose sale to the U.S., the vaccine could bring AstraZeneca \$2.15 billion in revenue.

While \$2.15 billion would represent almost 7% of 2008 total revenue, there are a few things standing in AstraZeneca's way. Unlike most H1N1 vaccines, AstraZeneca's is delivered nasally, which means that a sprayer must accompany each dose. In July, Brennan explained that filled doses were limited by the availability of delivery devices, but noted, "We are taking steps to increase the supply of sprayers."

AstraZeneca's supplies are expected to be the first doses of H1N1 vaccine to arrive in the U.S., according to a September 18 announcement by the CDC. According to *Reuters*, CDC spokesman Dr. Jay Butler said 3.4 million doses of the vaccine are expected to be available by the first week of October.

Like the other large-cap vaccine plays, AstraZeneca has a lot on its plate, and H1N1-driven sales are more of a cash flow-booster than a significant driver of bottom line performance. On September 24, Goldman Sachs turned bearish on AstraZeneca, cutting its rating to Sell from

Neutral. The analyst cited the upcoming court hearings over cholesterol drug Crestor. Further review of pending legal issues should be made before investment in the stock.

## Baxter International

Deerfield, Illinois-based **Baxter International (NYSE: BAX)** is the only large-cap swine flu vaccine maker based in the United States. Although it is not one of the five companies selected to provide the U.S. with pandemic vaccines, it will supply many other nations, including New Zealand, Ireland, and the U.K.

While some vaccine companies continue to fight for a bigger share of the global pandemic market, Baxter stopped taking orders in mid-July. A company spokesman said "At this time we're not in a position to take additional orders," according to *Reuters*. Based on the 80 million orders the company did accept, it could bring in more than \$850 million in swine flu sales, the equivalent of about 7% of the company's full year revenue in 2008.

At a September investor conference, the company said it delivered the first dose of its Celpavan H1N1 vaccine within 12 weeks of receiving the virus strain from the CDC. By September 16, it had shipped Celpavan to four of the five countries from which it accepted orders. On October 7, the company announced that European Union regulators approved Ceplivan, according to *The Wall Street Journal*.

According to coverage by *Barron's*, Baxter expects annual revenue growth of 7% to 8% over the next five years. The newspaper was bullish on Baxter, citing "an attractive combination of modest valuation, healthy growth prospects and insulation from possible reform measures." The near billion-dollar vaccine sales would help the company get a good start on its revenue growth guidance.

## A Major Flu Outbreak Would Impact a Wide Array of Sectors

While quite a few stocks have seen upside moves thanks to swine flu news in 2009, many more stocks are exposed to potential downside if the H1N1 pandemic. With that in mind, there are a few sectors investors should keep an eye on as we enter peak flu season.

### Travel

The looming threat of a severe H1N1 outbreak has the potential to weigh heavily on the travel industry. Businesses are already taking extraordinary measures to protect their clients and employees from infection, and hype surrounding the issue could lead families to cancel holiday travel plans.

According to *The Wall Street Journal*, Barclays said that airlines lost an estimated -\$400 million or -2% of total second-quarter passenger revenue because of the April swine flu outbreak. With expectations of a more severe outbreak at the height of the upcoming flu season, a more significant decline could weigh on performance in coming months. The analyst also noted "most airlines are struggling with liquidity concerns and need a sustained revenue recovery." This being the case, a demand slump could have an even larger negative impact on these stocks.

**Southwest Airlines (NYSE: LUV)**, **Delta Air Lines (NYSE: DAL)**, and **Continental Airlines (NYSE: CAL)** are among stocks poised to struggle amid a "sustained and material outbreak," according to *WSJ* coverage of Barclays' report.

According to a September 15 report by *Bloomberg*, the demand for charter services has increased as a result of swine flu fears. Warren Buffett's **Berkshire Hathaway (NYSE: BRK-A, BRK-B)** could benefit from the trend via its NetJets private aviation unit.

CDC infectious disease expert Dr. Michael Bell told *Reuters* that flight attendants and other employees that move throughout the cabin can spread more germs than passengers, who for the most part remain in their seats. On cruise ships, however, passengers are not confined to a single location, and are free to spread germs anywhere on the ship, while relatively close confinement puts other vacationers at risk of infection.

**Carnival (NYSE: CCL)** and **Royal Caribbean Cruises (NYSE: RCL)** are on Barclays' list of travel stocks to sell in the case of an outbreak. Royal Caribbean cancelled some cruises and rerouted others away from Mexico during the second quarter, according to *The Miami Herald*. Still the company lost -5 cents in EPS for the period because of "that damn flu," as worded by CEO Richard Fain.

When cruise ships alter itineraries to avoid problem areas, it can mean more days at sea and fewer at port. This is good news for cruise line spa services company **Steiner Leisure (NASDAQ: STNR)**. When asked about the impact of swine flu during the company's first-quarter earnings call, president and CEO Leanoard Fluxman said, "anything that gives us another sea day,

typically is a positive takeaway, not a negative," though during the Q2 earnings call Q&A, he explained that the positive impact of the swine flu was not material. However, a focus on staff management in relation to demand should keep the H1N1 virus from weighing on Steiner's shares.

Regarding hotels, those with a significant presence in regions of severe outbreaks will likely be the most affected, although an overall decline in travel would hurt the sector across the board. The Hotels.com HPI tracks pricing trends based on rates actually paid by customers, not those advertised. According to *Reuters*, swine flu was a factor in Latin America's -18% price decline, the steepest year-on-year drop of any region as of the latest index, which covered the first six months of 2009.

Barclays mentioned that **Marriott International (NYSE: MAR)** and **Windham Worldwide (NYSE: WYN)** were among stocks that could see pricing pressure similar to that which followed the spring H1N1 outbreak in Mexico.

## Restaurants

The restaurant sector is among those set to fall in the event of a severe swine flu outbreak. In order to protect themselves from possible infection, would-be patrons are more likely to eat in under pandemic circumstances. While the entire sector is exposed to the threat, some stocks are more susceptible than others.

*The Wall Street Journal* outlined Barclays' picks to avoid based on swine flu in a report on September 3. The analyst said dine-in restaurant companies like **Cheesecake Factory (NASDAQ: CAKE)**, **Brinker International (NYSE: EAT)**, and **Chipotle Mexican Grill (NYSE: CMG)** are more exposed than drive-throughs. While we agree with Barclays that dine-in restaurants are the most vulnerable, we think that those with operations in densely populated urban areas stand to be hurt the most upon an outbreak.

High end steakhouse operators **Morton's (NYSE: MRT)** and **Ruth's Hospitality Group (NASDAQ: RUTH)** are threatened in particular due to their urban locations and dependence on business spending. In August, S&P Research analyst Mark Basham told *Reuters*, "Business travel is likely to remain very weak over the next two quarters. More than the average restaurant, Ruth's is dependent on business travel for dragging traffic into its restaurants." Morton's is in the same boat, and if swine flu were to depress business travel and entertainment even further, these stocks could be in trouble.

Companies like **Dominos Pizza (NYSE: DPZ)** and **Sonic (NASDAQ: SONC)** should outperform other dining stocks during a pandemic outbreak because they require minimal exposure to the public. In either case, whether it is Dominos' delivery pizza or Sonic's open-air drive-ins, consumers are exposed to a single server, and they don't need to leave the germ-free atmosphere in their home or vehicle.

As a whole, the restaurant sector is one to avoid in the case of a severe swine flu outbreak. If exposure is a must for a particular investment strategy, we advise that investors stick with names that offer minimal exposure to potentially contagious atmospheres. Meanwhile, companies like **Heinz (NYSE: HNZ)** should benefit as easy-to-prepare frozen foods could be an alternative for those trying to stay in. **Overhill Farms (AMEX: OFI)**, on the other hand, has exposure to the airline food market, which could be hurt if H1N1 weighs on travel.

## Retailers

In the case of a severe viral outbreak, consumers may opt to stay away from crowded areas like shopping malls and other retail outlets. With the holiday shopping season around the corner, the H1N1 virus could have a significant negative impact on the retail sector's fourth quarter performance.

Despite a decline in foot traffic at shopping centers, most public retailers have exposure to the stay-at-home shopping market via online catalogs. This being the case, it could be difficult to determine exactly which retail plays would be hurt the worst under pandemic circumstances. An alternative play on a boost in online shopping is shipping companies like **FedEx (NYSE: FDX)** and **United Parcel Service (NYSE: UPS)**.

Whether purchases are made from online shopping giant **Amazon.com (NASDAQ: AMZN)** or one of the many company-owned and operated retail sites, a shipping company will get a piece of the pie – and in many cases retailers will pick up the tab.

One brick and mortar retail sector could benefit from increased foot traffic as a result of the swine flu pandemic. Drug stores and pharmacies like **CVS Caremark (NYSE: CVS)**, **Rite Aid (NYSE: RAD)**, and **Walgreen (NYSE: WAG)** could see a demand spike for various over-the-counter flu remedies as well as preventative products like seasonal flu vaccines and hand sanitizer.

On September 29, Walgreen president and CEO Gregory Wasson said the company already provided more than twice as many seasonal flu shots as it had throughout the entire course of last year's flu season. In addition to the direct benefit of vaccine sales, the company should also continue to benefit from residual sales from customers visiting the store for flu-related reasons and buying other goods out of convenience.

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