UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 22, 2022

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35285**	**59-1212264**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

170 Harbor Way, Suite 300, South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 550-3500

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	**VXRT**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On June 22, 2022, Vaxart, Inc. (the "Company") held a live question-and-answer session via webcast with investors to provide an overview of the Company's oral vaccine programs and to discuss the proposals being submitted at the Company's annual meeting of stockholders, which is now being held on July 6, 2022, following its adjournment.

A copy of the Company's investor questions and answers is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Copy of investor questions and answers.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Vaxart, Inc.

Dated: June 28, 2022

By: /s/ Andrei Floroiu
Andrei Floroiu
Chief Executive Officer

REFINITIV STREETEVENTS

EDITED TRANSCRIPT

VXRT.OQ - Vaxart Inc to Host Investor Q&A Webcast

EVENT DATE/TIME: JUNE 22, 2022 / 5:00PM GMT

REFINITIV

CORPORATE PARTICIPANTS

Brant Biehn Vaxart, Inc. - SVP of Business Operations

Cezar Andrei Floroiu Vaxart, Inc. - CEO, President & Director

James F. Cummings Vaxart, Inc. - Chief Medical Officer

Sean N. Tucker Vaxart, Inc. - Senior VP & Chief Scientific Officer

PRESENTATION

Operator

Greetings, and welcome to the Vaxart investor Q&A webcast. (Operator Instructions). A question-and-answer session will follow management's opening remarks. As a reminder, this conference is being recorded.

I will now like to turn the conference over to your host, Brant Biehn, Senior Vice President, Business Operations.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Good day, everyone, and welcome to today's call. Joining us from Vaxart are Andrei Floroiu, the Chief Executive Officer; Dr. Sean Tucker, our Founder and Senior Vice President and Chief Scientific Officer; and Dr. James Cummings, our Chief Medical Officer.

But before we get started, I'd like to remind everyone during this conference call that Vaxart may make forward-looking statements, including statements about the company's financial results, financial guidance, its future business strategies and operations and its product development and regulatory progress, including statements about its ongoing or planned clinical trials.

Actual results could differ materially from those discussed in these forward-looking statements due to a number of important factors, including uncertainty inherent in the clinical development and regulatory process, the extent and duration of the impact of the COVID-19 pandemic and other risks described in the Risk Factors section of Vaxart's most recently filed annual report on Form 10-K and other periodic reports filed with the SEC. Vaxart undertakes no obligation to update any forward-looking statements after the date of this call.

I'll now turn the call over to Andrei for initial remarks. Andrei?

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Thank you, Brant. So let me start by thanking you for being Vaxart investors, particularly now in this stock market downturn. During the years I was a biotechnology investor on the institutional side, I learned that investing in biotech requires not only a lot of conviction, but often a lot of resilience and patience, particularly in downturns. So I really then -- given that this is one of the most severe downturns we have seen in the sector in the past 20 years, I wanted to thank you not only for investing and believing in us in the first turn -- in the first place, sorry, but for sticking with us through this downturn.

So we are all here today because we all want Vaxart to be a success. And that success is important because Vaxart is working on transformative innovation, which has the potential to make a significant impact on people's lives globally on how we continue to fight this pandemic and potentially on how we are going to be prepared to fight future ones. We are all here today because we believe passionately in our company's potential and mission. But we are also here today because we'd like to communicate better with you. So our main goal on this call is to answer your most pressing, most frequently asked questions.

Now most of the questions from you that I have seen relate to the past 6 months or so. However, I think that our answers will be much more informative if I take a step back first and put everything in the context of our progress over the last 2 years. I'll give you a quick overview of how far

we've come over the past couple of years, a summary of our achievements, the context you need to accomplish them, but I also want to talk about our challenges and how we plan on addressing them. Then we'll have the Q&A session, which is the main part of this call, which will be run by Brant, our SVP of Business Operations.

So let me start to that context I mentioned. When I arrived at Vaxart, was 2 years and 1 week ago, we had 11 employees. So we relied on outside suppliers for most of the work we've done, including for manufacturing, and that outsourced model was very common, was normal in the pre-COVID-19 era. But COVID-19 changed everything. Nothing was normal anymore. So we soon realized that before we could transform the vaccine space, we actually had to transform Vaxart itself.

And why is that? Well, many biotech companies realized that the outsourced model was failing in the post-COVID era, actually in the post-COVID world, if I can say. Things were even more acute in the vaccine space because everybody, all of a sudden, was rushing to develop COVID-19 vaccines. So you've seen this significant spike in demand on limited resources that are also operating below capacity, given the pandemic. So many suppliers were overwhelmed, turnaround times lengthened and quality often suffered.

And so back then, all of us said that in order to maximize our chance of success, we have to internalize as many capabilities as we could and do so in the shortest time possible. And this was easier said than done because remember, 2 years ago, we're during the first COVID wave, during lockdowns, and this was before vaccines were available. So in that situation, during those lockdowns, 11 of us embarked on the daunting task of transforming the old Vaxart into today's Vaxart.

Vaxart today employs over 150 people, has a much stronger management team. We own 2 manufacturing plants, new labs for research, new labs for development, new labs for CMC and so on. And that's very important. And let me stop here for a little bit, because I believe that today's Vaxart is in the strongest position it has ever been in its 15-year existence, and that is very significant. So accomplishing this transformation in such a time during the pandemic, I believe, is a momentous achievement.

But growing our number of employees 15-fold during a very competitive biotech job market, transforming Vaxart, transforming the way we work, it's not the only thing we have achieved over these past 2 years. So I'm going to give you a list of some of the achievements.

We started a COVID-19 program. We restarted the norovirus program. We started 6 clinical trials, we finished 4 of them, 2 of them are ongoing. We had discussions with regulatory agencies in 5 countries, 5 -- 2 INDs here in the U.S., 1 city in India and had conversations with 3 other -- regulatory bodies in 3 other countries. We started and performed 8 major preclinical trials. We filed for 4 patents, we published 5 publications, and I could go on and on.

During these 2 years, we raised almost $0.25 billion, and we also obtained favorable coverage by 4 new Wall Street analysts, some of which are among the most notable on Wall Street. And so we achieved all this over the past 2 years. And what makes these accomplishments even more notable is that we achieve them during the COVID-19 pandemic.

So this pandemic appended our lives personally very dramatically, and I think we all know that and have many examples of that, although what may be less visible is that the pandemic impacted businesses often in much deeper ways. All of a sudden, we're operating in uncharted waters for which there are no playbooks, so I mentioned that all models started to fail, supply chains were stretched, and the impact on businesses like ours was even more acute because the remote model doesn't apply to many aspects of our business. So when people get sick, labs close. When people get sick or need to be quarantined, manufacturing GMP plants close, all these caused delays.

And at points, it got even worse because the health care system got overwhelmed at various times as the COVID waves ebbed and flowed, and that caused delays to clinical trials. So in this new unprecedented reality, our ability to plan and project was challenged in many unexpected ways. So it is in this context that we have had an uneven record of predicting clinical and preclinical deadlines. However, overall, we are extremely proud, and I believe you should be extremely proud of what we have been able to achieve in this most challenging of circumstances.

And let me just illustrate that a little. At the recent World Vaccine Conference, one of our big pharma partners[1] mentioned that they were extremely impressed by the fact that last year we're able to run 5 clinical trials in parallel during COVID. So what you should take away from this is that if at times we have been late, it was because we are reaching for the moon, we're trying to do more than much larger companies thought possible.

Now that being said, of course, there are things that we can do better. And one of them is to improve the accuracy with which we guide on time lines. And if those time lines change, we'll try to explain better what caused it. And that takes me to the second thing that we can do better, and that is communicating with you, our investors. We are aware that we could communicate better with you and more frequently, and we intend to do both. This call is the first concrete step. We also will start having quarterly conference calls and are also thinking about other ways in which we could help you understand better in a more timely manner our progress.

And with that, I'd like to turn it back to Brant.

QUESTIONS AND ANSWERS

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thanks very much, Andrei. So we have lots of questions. Thank you all for submitting so many questions in advance. And also we have a number of questions coming in now live as well. I think the most common question relates to COVID-19, our Phase II trial and why it's delayed. I'll just read one here. James, this is a heads up for you to answer. And the question is why have there been repeated delays in the time line for the COVID-19 Phase IIa trial? James, over to you.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks, Brant. So I'd break down delays when they've happened into a couple of buckets. First, recruiting and enrolling during an active pandemic has proved challenging. Some of the volunteers we enroll become positive during the study, and many more volunteers become positive prior to immunization, which requires us to go out and find new replacement volunteers.

This study, as you may remember, is one that looks at boosting previously immunized folks with our vaccine as well as immunizing vaccine-naive volunteers, meaning some people who haven't received any COVID vaccine. Well, the reality is there aren't a lot of people left to participate in a vaccine study that haven't already been immunized with the previous COVID vaccine.

We know how important this data is to determining our next steps in our COVID program. And we've been very eager to get to the data as soon as possible. We actually went back a short while ago and took another look at what data we would need and adjusted the total number of volunteers to be enrolled in Part 1 of our Phase II study. That's now at 66 folks to allow us to get actionable data for Q3 and 2023.

The second Andrei has highlighted just previously, it's COVID-19 and its impacts on lab analysis and supplies. Many groups are trying to use the same or similar supply chains and external labs to support their studies. And this causes congestion and causes things to slow down. Even internally at Vaxart, we've had some work slowing because members of our own team have come down with COVID-19. And this is true, not just in our industry but really in many industries across the board, and that impacts the speed that we can move things forward. All that said, we've done our utmost to move the schedule forward, and I'm very proud and impressed with what the team has achieved under these circumstances.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, James. So the next one staying with COVID, and Sean, this is more of a preclinical question. So question reads, it does not look like you will be moving forward on the COVID S+N construct. Is that correct? And there's another one here shortly after, it was in same lines. When will you decide which one to move forward and what will drive your selection process? Sean, if you could tackle that, that would be great.

[1] Intended to say "peers", not "partners"

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Yes. Obviously, there's been some confusion out there, but we have -- it's still early stages for us. And as James mentioned before, we're gathering data on the S-only construct, and we'll have data in Q3. But we are also still gathering some information on the S and N construct, basically how long lasting immunity does it -- how long does it last? And those are important things for us going forward.

And in addition, we're also looking at the original Wuhan-based vaccines versus Omicron-based vaccines, and we'll decide whether this should be part of our equation. Keep in mind, one of the things that's been proposed by some of the injected vaccines, such as Moderna, is to take a bivalent approach. And these are all things that we'd like to have and make a decision in the next quarter.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thanks, Sean. And staying within S and N, it's another question for you, Sean. Why do you think the S and N COVID vaccine produced less serum IgG than the S-only?

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Yes, it's a good question. And one of the things that we point out is that this is a study that was done in a preclinical model. So again, we still have to evaluate it in humans. But what we found is that in the NHP model, specifically cynomolgus macaques, we saw less serum responses with the S+N construct in comparison to the S construct. And again, this is something we published. We don't quite know the reason, but one of the things that we think, or the hypothesis, is that the S and N may be much more potent for T cells and less potent to the antibodies. And as I mentioned before, this is something we'll need to do -- it's still a hypothesis and we'll still need to verify in humans.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Got it. And staying within the same questioning realm, the N protein was supposed to improve cross-reactivity in T cells. Does the S-only result in less T cells as a result? Sean, again, please.

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Yes. Obviously, the N protein is nice from the standpoint it's more conserved among all the SARS-CoV-2 variants. But the S protein is very large. And in fact, a lot of the mutations aren't happening in the T cell epitope. They're happening outside of that. And so we still think because the S protein has a lot of those epitopes still available, it's still a really good target. So again, as we go forward, we'll evaluate in the current studies we're doing and see whether the T cell responses are still robust. But again, we think the S protein is a very good T cell target.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. And then we'll move back to a clinical question. Again, this one, James will be for you. So the question is you mentioned at Jefferies, you may do a human challenge study for COVID. What do you expect to get from that, James?

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Right. So I think that a human challenge study for COVID-19 can have really a lot of advantages. When you're looking at a correlative immunity from that challenge study, we're primarily looking at IgA ASC cells that we've again had a really good fortune of producing with our construct. And we're also looking at those CD8 mucosal T cells that looks more towards the modulation of severe disease and death, et cetera.

When I look at regulatory pathways, we have certain strategies, I think, in the U.S. and outside the U.S., right? But this challenge study helps inform it. Another benefit of that challenge study would be to help shape what would be or could be a Phase III study. Clearly, if you have known and verified or validated correlates of protection, your Phase III could be a smaller study.

And looking at the impact of our product it has on boosting those who've already been immunized, safety is always a primary concern, but we're also looking at immunogenicity, immune correlates, as I mentioned. We're looking at preliminary efficacy both from sterilizing immunity as well as preventing symptomatic disease and the impact our vaccine would have on viral shedding. These are all very important readouts that one can obtain when doing a very carefully controlled challenge study.

From a COVID standpoint, that virus continues to mutate. I think the good preliminary information we have is that because our approach is IgA, we have a much broader branching, somewhat stickier approach helping out on what variants might arise. As opposed to a more traditional, let's say, mRNA or other construct, which does develop serum IgG, but when you think of that, that's more of a very specific lock-and-key type of mechanism that really doesn't yield itself well in the face of upcoming variants.

We know that RNA viruses have a very weak editor. So it's not if variants are going to occur. They're going to occur, it's just when. And when you talk to most modelers or people who are really in the know, in the industry, it's likely 3 to 4x a year we'd expect to see a new variant.

So if -- by the time you have developed your construct, you've tested it and you've gotten it approved, you're likely going to be already a variant or 2 behind. And if what you put out gives a very specific immune response that doesn't provide cross protection, you've lost before you even got off the block. So I think we have a broader-based immunity, and I think that does give us a differentiated product.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thanks, James. Sort of just a quick add on to that as well. So for the human challenge study for COVID, will there be a comparator to an approved vaccine, similar to what was done in the flu challenge study? James, to you.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Yes. The landscape of COVID-19 vaccine development, it's changing all the time. That said, there could be a comparison in a Phase III clinical trial to follow our current Phase II data inflection points coming up. And we're still in negotiations for a COVID challenge study. After contracting for that study, we'll solidify the design.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you. All right. We'll switch gears a little bit, still staying on COVID, but James, another clinical study. So the question is, why haven't you started the India trial yet? Wasn't it supposed to start earlier this year?

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Yes. Thank you. So you may have seen some tidbits in the press about India and us. And just so you know, we've approached the regulatory authorities in India regarding our COVID studies as both a boost as well as a vaccine for vaccine-naive population if possible, and it's been fairly well received. Now that said, the Indian regulatory pathway, many regulatory pathways, they take time.

Also, our vaccine is novel compared to the injected needle-driven vaccines that are available. So testing of our product really requires the Indian regulatory authorities to enhance our capabilities in terms of evaluating our vaccine candidate, and we're giving some assistance there. We look forward to embarking on our vaccine study in India once regulatory review is completed. COVID data that we'll have from our Phase II Part 1 in America will help further refine this study moving forward.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, James. All right. Andrei, we'll need to get you in on some of the questions here. Here's a good one. Proposal number 2 on the proxy asks for an increase in the number of authorized shares. Won't this be highly dilutive for about 40% to existing shareholders, Andrei? Andrei, you may be on mute?

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Thank you, Brant. Yes, I was on mute. Thank you for that. So unfortunately, I've seen this question quite a lot, and this is far, far from the truth. No. Passing number 2 -- proposal number 2 will not cause a 40% dilution to shareholders. I think this is a big misconception, and I think for your benefit as shareholders, it's important that we understand what this proposal does and what it doesn't do.

So we'll continue to use the shares that we have authorized very thoroughly[2] and opportunistically, as we have done in the past. And I think you have these past 2 years to look at and get a sense of what will happen to the shares.

As I mentioned before, over these past 2 years, we raised almost $0.25 billion, but importantly for you, shareholders, we've done it in a very shareholder-friendly way. We did not use marketed offerings, which are quite common, but instead relied on at-the-market offerings, which is called ATMs. And by doing so, we're able to pay lower banking fees and raise a lot more capital than we could have through traditional marketed offerings.

And let me try to put some numbers behind this. So last year, in 2021, we raised $128 million in gross proceeds by issuing approximately 13 million shares at $9.66. Now this price is 30% higher than our average closing price over 2021. So we are able to raise funds at a much higher price than the average price. And that resulted in us raising $30 million more than if we had sold shares at average prices.

It gets even better. If you consider the fact that through an ATM, we didn't have to give the discounts that you typically have to give to marketed offerings that we paid lower banking fees, we estimate that we actually raised only last year $50 million more than we would have through marketed offerings. And that all is value that accrues to you, the investor. And I think that's significant.

Another thing that I think is very important by being thoughtful and opportunistic in how we raise money, we started this year in a very strong financial position. So when this downturn was ongoing, we were not in the precarious position that you see many other biotechnology companies have been. And passing proposal number 2 is very important in allowing us to continue to do so, to continue to be in a strong financial position so we can continue to execute. Thank you, Brant.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, Andrei. And so staying within the same theme, another question about proposal number 2. So does proposal number 2 benefit insiders? Why do you need all the extra options? Back to you, Andrei.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Thank you so much. So kind of 2 questions there. Again, a major misconception about proposal number 2. Proposal number 2, clearly benefits the company and its shareholders. And I'll try to touch on this in a few different ways. So first, I'd like to remind you that the 2 leading proxy advisory firms, ISS and Glass Lewis, came out in support of proposal number 2.

Now their job is to opine on which proposals are benefiting the shareholders, not management, not insiders. That's not what the proxy advisers do. They just read the proposals in terms of whether they believe they will benefit the shareholders. In this case, clearly, they said that this proposal benefits shareholders.

[2] Intended to say "thoughtfully", not "thoroughly"

Now the other thing I wanted to touch on, there is no dynamic here of shareholders versus insiders. Management's interest, as are the interest of all employees at Vaxart, are highly aligned with those of shareholders through the stock options that we have, and therefore, we have a significant economic value in creating shareholder value here.

Now let me try to explain how proposal number 2 benefits the company and therefore, you shareholders. So fundamentally, proposal number 2 will allow us, give us the flexibility to continue to be, as I said in my previous -- in the previous question, to be thoughtful and opportunistic in raising capital so we can fund the business, so we can maintain a strong balance sheet as we progress our programs.

And being opportunistic is very important, right? The market could rebound. COVID-19 stock could become "hot" again. We could put out positive data and our stock may react positively. So it's very important in a market that is volatile, with the stock that is volatile that you have this flexibility to be opportunistic and continue to raise funds on terms that are very favorable to investors.

But this is not the only benefit. More generally, continuing to maintain a strong balance sheet has so many benefits for us. It makes us a more attractive partner to governments. It puts us in a stronger competitive position. And it also allows us to fend off lowball takeover attempts, particularly at these depressed levels.

Now the question also asked something about options, which is actually a different proposal. But it depends on proposal number 2, and I think it's very important. Passing proposal number 2 will allow us to continue to use options as a tool to attract talent, to retain talent and importantly, to align our interest with those of you, the shareholders. And it's very important that we have that tool.

Now, also stock options, interestingly enough, allow us to select the right employees. You don't want people to come to Vaxart just because they want the job. We want people to come to Vaxart because they are passionate about the work we do as much as we are, as much as you are. And I'll give you one great example of how this can happen.

So Dr. Cummings joined Vaxart last year by taking -- accepting to take a pay cut. So his salary at Vaxart was lower than before. And part of why he accepted to do that is, of course, because he is passionate and he believes in the mission we have. But the other part is that the stock options that he was granted upon joining allowed him to have an economic stake in the value creation that we all want to do here in Vaxart. So we'd like to do more. We'd like to check more people like James. And again, passing proposal number 2, being able to offer options is very important for us to be able to do that.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, Andrei. And you mentioned partnering with governments. There's another question here that I'll read out now pertaining to that. Pfizer and Moderna received a great deal of government funding for their COVID-19 vaccine programs. Will Vaxart receive any U.S. or international government funding for your vaccine? If not, why? Back to you, Andrei.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Not an easy question to predict what governments are going to do. So let me see. We remain very hopeful that governments, particularly rich governments in the developed world, will finally realize the need to invest in next-generation vaccines, both for this pandemic and future ones. I believe that chance is higher now after the Omicron wave because they have seen -- we have all seen the limitations of first-generation vaccines than before. And so we continue to have positive interactions with governmental bodies both here in the U.S. as well as abroad. But again, it's very tough to predict what governments will do. Let me give you an example.

We worked very hard to lobby the U.S. government for passing the COVID-19 bill that is now through Congress. And we're even able to suggest language, to contribute language to that bill. And for some time, we were very hopeful that this bill was going to pass a couple of times. But then much bigger political forces intervened, and now it's uncertain what's going to happen to that bill.

So we remain hopeful and active in trying to persuade governments of their need to support work like what we do. But it's important to realize that we cannot rely on government funding. We have to be able to self-fund, so again, passing Proposal No. 2 is very important in allowing us to both continue to self-fund as well as continue our awareness and lobbying activities. Thank you, Brant.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you. All right. Let's switch gears again and we'll go back to clinical. James, you'll be up to this one. Several COVID-19 vaccines are already FDA approved. Is there really still a market for Vaxart's vaccine, James?

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Well, we sure think so, and we're not alone. The Washington Post, New York Times and a large amount of the scientific community, to name just a few, believe that the way forward with so many vaccines is mucosal vaccination, producing cross-reactive IgA in the nose. Our Phase I study was a very positive step in that direction. And now as Sean mentioned, we're trying to improve on that.

Looking at broader branching immunity and from a global health standpoint, being able to deploy a tableted pill, a vaccine that can be done in a country in a matter of days to weeks rather than months, would be a game changer. We've had very interesting conversations with government health care systems in Europe who certainly aren't necessarily resource constrained, but they've had a very difficult time in fielding a coordinated effort to jab as many members of the population as they could to receive that vaccine. It took them over 6 months. To think that people would be able to get 4 jabs in a year or 3, it's really untenable. And that's just for those countries that are well resourced.

And there's a very good editorial in the New York Times in February from the then Director of the Africa CDC. And I'm going to paraphrase it, but he said very clearly, we can't accept any more vaccines for COVID because I don't have the logistics to supply it and store it. I don't have the cold chain. I don't have the needles, syringes or medical personnel to deliver it.

And that's in a resource-constrained environment where with a thermostable approach, not only could we immunize those folks, but from a global standpoint, the rapidness with which we could deploy our vaccines really would bring herd immunity to the forefront much quicker. And we've already mentioned the idea of a broader immunity. So I think there's potential for some benefits there.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, James. So we'll switch gears a little bit. We've been talking about a lot of COVID and some of the proxy questions. This one is going to be, James, you're going to be up again. The question pertains to norovirus vaccine. And it's quite simple, why you keep talking about norovirus. James, over to you.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks. So there's a very good paper that came out from Johns Hopkins that looked at the financial impact of norovirus. Just here in the United States alone. And it looked at the medical treatment and the issues that older individuals with comorbidities have. And then it also looked at the economic impact, not just to the medical treatment of children, but the parents who can't necessarily send their child to daycare or school because the child has norovirus. And the number they came up with for the economic impact of norovirus just in the United States was $10.6 billion a year. That's the cost impact of that disease, $10.6 billion a year just in the United States. I think that's a fairly significant number. And when you're looking at resource allocation for health care, I think it deserves a response. It deserves a vaccine.

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

If you don't mind, I'd love to jump in here, Brant. Again, the question is that one of the reasons why we talk about this indication is we're just really excited about it. Most people believe that norovirus is just something that caused issues on cruise ships, closing of schools or summer camps, but everybody gets norovirus infection. And we know it's extremely contagious. And we know that the very old and the very young are the ones that have the worst outcomes. Certainly, the elderly can potentially die from the illness and/or have, again, very severe outcomes.

The reason what we're just -- we just talked about recently in the press was we completed a study in the older folks 55 to 80, and we got some really, really impressive immune responses that were really similar to what we got in younger folks, and this doesn't happen with every vaccine. And so we're very excited because this data is the kind of data we need in the actual -- people that are actually going to benefit most, and that's a key aspect of this approach is that we basically, we now have data that says that our vaccine is working well in a population that could actually benefit substantially from it. So again, we're really excited about norovirus, and we're really excited about the data we have.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

I'd actually like to add something here. So let's make this question, one that all 3 of us respond, I think because we feel pretty great about norovirus, this is something I didn't know much about before I joined Vaxart. But over the past 2 years, we've educated so many investors, including very sophisticated institutional investors on norovirus. I think what's interesting for you, the shareholders, is that once you start talking about norovirus, you realize how many people actually suffer from norovirus or know somebody that did.

This is something that people didn't talk about because there is no treatment. And again, they thought it happens just on cruise ships. I've seen over the past years, so many people say, "Oh, I suffered, my kids." Only last week, I was interviewing for our CFO position. And the gentleman I talked to said, "Look, I had an episode of norovirus, and it was quite bad." So again, it's a big disease. As James said, it’s big and it's much more prevalent than you think once you start talking about it.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you all 3 for commenting. So let's stay on norovirus. Another question that we have in is what are the next steps on the norovirus program. James, I think that comes to you.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks. So as many of you may know, we're in the midst of our norovirus challenge study, so a G1.1 challenge, where we've immunized our folks with our norovirus vaccine or placebo and then challenged them with the G1.1 strain.

There's 2 predominant strains of norovirus in circulation that cause the majority of diseases, that's G1.1 and GII.4. There is a G1.1 challenge that's very well described, well known and safe. And so we're in the midst of performing that immunization and challenge study that will immunize and challenge with either our product or placebo.

We're looking at 100 individuals to go to challenge. We'll put 123 immunization because we want to make sure that we have a full component of people to bring to challenge with norovirus. And by challenge, what I mean is, after immunization and their immunity has built up, we give them a very carefully selected safe dose of norovirus that induces, or doesn't if they're protected, acute gastroenteritis.

What we look forward to is getting some data in terms of the immunogenicity and then also looking at the impact of our vaccine on the presentation of symptomatic gastroenteritis or acute gastroenteritis from norovirus. And that's, again, something that will allow us to qualify our immune correlates as we look forward and can impact a larger study in a Phase III.

Next steps to me would be a dose confirmation study, and that could be pushed out in the future as we gather more data and then potentially an age de-escalation study because as Sean mentioned just now, norovirus really, it's at both ends of the age spectrum of our society. The more mature and older population and the younger population is the most impacted by this disease, but really everyone gets exposed and everyone, unfortunately, can be impacted.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Fantastic. Thank you. We'll switch this one back to Andrei. So question I think you hit some of this in your opening remarks, but probably best to tackle it as well. So the question is, you haven't done a good job of communicating with shareholders when trials or data reporting are delayed. Are you going to fix this? And if so, what's your plan for providing more timely updates? Andrei.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Thank you, Brant. So yes, I can perhaps reiterate what I said before. But the one thing I didn't say that I could add here is that I'd like you to understand this was not by design. So hopefully, by understanding our progress and transformation over the past 2 years, we can start to understand that our focus has shifted. And so initially, our focus was very much on pushing forward the COVID clinical program on actually funding the company, raising funds, the first $100 million we raised were from institutions.

So naturally, we focused on that. And then on transforming the company and on trying to generate data, and so we have been slow to change our focus more towards individual shareholders as our shareholder base has changed. But as I said, we recognize that's something we need to do. We actually want to do that. You, the investors should be our biggest supporters, and so we are very keen on continuing to do what we've done today, I said through quarterly calls, and we'll try to think about other ways to keep interacting.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, Andrei. And we'll go with the next question for you as well because I think it's a good one. So what milestone should we look to overall for the rest of '22 and '23? Andrei, to you.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Yes. So I think, I mean I think we have a very exciting 6 to 9 months here in front of us. The first big one is, of course, the COVID -- the preliminary data from the COVID Phase IIa study. And after that, as James and Sean alluded, we're going to work on deciding which constructs to push forward, and we'll communicate, of course, after that, the next steps in our clinical program for COVID, and we're going to clarify those.

Also on norovirus, we're going to be able to comment on the progress of that study. Then in the -- this will also be in the second half of this year. Then also in the second half of this year, we'll publish more detailed scientific data from some of our clinical and preclinical studies. And towards the end of the first quarter 2023, we'll have the preliminary data from the norovirus challenge study. So again, I think lots of events over the next 6 to 9 months. And I think a very exciting time here to be following that side.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you very much. Another question that we do get quite often is Vaxart trying to establish partnerships with any of the big pharmaceutical companies? So Andrei, I'll have you speak to that one as well, please?

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Yes, yes. The answer is obviously yes. We've always been open to evaluating partnership opportunities both for the COVID-19 program as well as for other programs, both here in the U.S. as well as abroad, and we continue to remain open.

But it's very important here. Again, I'll go back to Proposal No. 2, it's very important that you are not forcing a partnership because you have to. It's very important that you go into these partnerships at the right time and try to obtain the terms you can. And to do that, you need to have the financial resources to be able to go it alone at the same time at which you negotiate partnerships or look for them.

So in the past, again -- in a distant past of this company, for some programs, the only option that the company had was to partner, and that actually hurt it, that slowed down programs, that led to programs being stopped. We don't want to be in that position again. I think partnerships are an important avenue for us to create value, but we want to do it on our terms. So again, passing Proposal No. 2 is very important.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you. Here's another question that we do get quite a bit, and this one will be for James. So the question, James, is what's going on with Johnson & Johnson and your flu vaccine program? James.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks, Brant. So we and many other companies have prioritized COVID-19 as a respiratory pathogen of interest for our vaccine development portfolio. Really, it's taken premise. That said, we continue to have discussions with J&J and others regarding our flu program which has shown positive results with numerically, although not statistically, better protection and statistically better decrease in viral shedding compared to Fluzone and that was published in Lancet 2020 -- Lancet ID.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, James. Another question for you, back to COVID again. So if your COVID vaccine does not produce serum antibodies in a human trial, does that hurt regulatory approval? James.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

That's a good question. So certainly, serum antibodies such as IgG as a measure is used for the current injectable -- needle injected COVID-19 vaccines that, as I've mentioned before, have been rendered potentially less effective by the new strains of this constantly evolving virus.

Our vaccine platform produces a boost to mucosal immunity and a strong T-cell response which can afford strong cross-strain variant protection as well as a very robust T cell-mediated immune response, which is important for modulating symptoms and severe outcomes, but this also emphasizes the value of a challenge study so that we can present to these agencies or immune correlates.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, James. And you're mentioning cross variants. Next question is one for Sean and it has to do with different variants. So this question is some vaccine companies are working on Omicron constructs, is Vaxart? Sean, over to you.

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Sure. Yes. Obviously, it's a very interesting question, and there's a lot of interest in the world because the current vaccines don't respond too well right now to the current -- the circulating strains of SARS-CoV-2. For example, do you know that the mRNA vaccines don't do as good a job against Omicron as they did against with the original parental Wuhan strain. Several months ago, we decided we were going to test our vaccine in a hamster challenge model using Omicron as the challenging agent. And what we want to do is to compare that to a vaccine that we made that contains just the S protein, but this time it was matched to Omicron.

And when we did this study, and again, this is a hamster model, not in human, the results suggested that our S-only construct with the original Wuhan was protected against Omicron as with the match vaccine, but this Omicron-specific vaccine made a slightly better serum antibody response, compared to the S-only from Wuhan. Obviously, we think there are potential benefits into making an Omicron specific vaccine given what's been going on in the world, but we have not made a decision yet whether we are to advance it. I mean, we'd have to put it in the GMP manufacturing before it could be put into humans.

And as we reported before, that our original S+N construct in human made a very strong cross-reactive IgA response through the nose. And those IgA responses were very cross-reactive against coronaviruses that were much diverse than SARS-CoV-2 Omicron or Delta, any of these variants of concern. So again, it's a really, it's a good question and something we have not decided one way or other yet how we're going to proceed.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Right. Just to follow up on that. There's questions on timing here, and maybe you can succinctly talk about the timing. So the question specifically is what's going on with the Omicron study? You just talked about it a bit. But the question says, you said December, the study would start in January and then February, it would start in March, and then there was no discussion about it in your May corporate update. Are you still doing the trial? Obviously, you just said you were, but maybe you could just respond to that, please, Sean?

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Sure. I mean, obviously, it was a very important question. We put out that press release in December, and we did talk about it in several different that we were going to do some evaluation. When we look specifically at the animal challenge study, we did state in December that we would start that animal study in January, and actually, the study did start in January. Our expectation was that would be read out in Q2. This actually used a prime and a boost followed by a challenge each a month apart. So you're talking about several months already. And of course, you do have the evaluation. We received the last of the data in May, and we reported the 3rd of June. This study was on time, essentially based on our expectations.

Keep in mind one of the critical elements, and again, James and Andrei have talked about this before, is that we're essentially having to evaluate how this does by looking at infectious virus. And those assays are run in BSL facilities that are really backed up right now due to COVID research. If it wasn't COVID, we might have been able to shave a few weeks off that time line, but not very much.

The other part of the evaluation we did mention in December was looking at our human vaccine results and looking at past tests' cross-reactivity in the serum and mucosal tissues. We're still working obviously on the primary endpoints of the Phase II human construct or human study for S-only as James mentioned, that's the readout in Q3. And so if we're not reading out the primary end point in Q3, we're not going to read out secondary endpoints as well.

We do -- keep in mind, we also have reported out data on the S+N construct Phase 1, and we did see that there was cross reactivity to all coronaviruses that we tested against, including species that are much more divergent from the new variants of concerns such as Omicron.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent, Sean. And still staying with you and staying on COVID-19, another question. Why do you keep conducting COVID-19 studies in animals? Don't you need data from human studies for FDA approval? Maybe you can opine on that Sean, please?

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Well, certainly, human data trumps animal data any day. But one of the key things that we're trying to address with animals, it's not very easy to do in small numbers in humans, is we want to know is our vaccine is still protected against the new variant, or does it need to protect -- or do we need to make a strain matched vaccine to make sure that has protection. And while the FDA may not require some of these studies, the data is important determining how we proceed and at what we do in terms of rate, and we may use that data from regulatory filings.

Let me tell you about one of the key studies that we did do that actually got a lot of attention, and that was the hamster transmission study. It was designed to prove that mucosal vaccine could block transmission to unvaccinated animals when there was vaccine breakthrough. And keep in mind, of course, not everybody in the world is vaccinated, like, for example, the small kids up until recently couldn't get vaccines. And it would be very easy to transmit to your unimmunized children.

So the theory we had was that if you've had enough antibodies in the nose, this would inhibit aerosolized virus transfer moving from an infected animal with breakthrough to another animal that's naive to vaccine through vial transmission. Obviously, and as I mentioned before, not everybody in the world is immunized.

One of the things that was interesting about this is this is something that your vaccine is essentially doing more than just protecting individual, you're basically protecting society, you're protecting other people. So it's kind of a very ambitious study from that standpoint.

So when we did the study, let me tell you a little bit about it, we observed that vaccination of hamsters orally or intranasally, and then if you could put those and then hit them with a large dose of vaccine and then put them in a situation where they were being able to exposed to naïve animal through aerosol transfer separated by a big tube. What you could basically find -- what we found out is those naïve animals exposed with the mucosally vaccinated animals, including orally, had a lot of protection against infection and severe disease. If you have be injected vaccines or the mock vaccine animals that created vaccine breakthrough, what you found is those naïve animals got really sick or basically, there was a lot of transfer.

And so this is something that's very exciting in terms of the field. We got a lot of -- once it was published in Science Translational Medicine, we've gotten amazing amounts of feedback from several nongovernmental organizations that were seeking to promote world health.

Of course, eventually, we have to prove our safety and efficacy in clinical studies in humans, but the preclinical studies that we're doing really help us in terms of our choice of vaccine and understanding the mechanism of mucosal immunity. And I think that's very important.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, Sean. So we're going to switch gears again, going back to the clinic and norovirus in particular. So James, you'll be up for this one. The question reads, why has the norovirus challenge data been pushed out? James, over to you.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks, Brant. So to be clear, our goal is always to conduct studies that produce the relevant data we need as quickly as possible. And whoever sent this question in, I agree with you. This has been frustrating. Here, in this case, delays due to product availability and delays due to COVID, they've occurred.

One of our manufacturing plants in Burlingame suffered from a flood last fall, when the municipal pumps shut down during a rainstorm in the San Francisco Bay Area. And water backed up, I think it was close to 3 feet deep around the building, right? We had to get that facility repaired, and back up to snuff for GMP manufacturing, so we could get the product we need to conduct the studies.

We also took that opportunity to upgrade some of the equipment and the manufacturing techniques. And although that took slightly a little more time than originally planned, ultimately, it makes the progress of our manufacturing that much better.

We look forward to sharing that top line data from that particular study, the double-blinded placebo-controlled challenge study when they're available in Q1 of 2023.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Just you've kind of answered it there. When can we expect interim data from the Phase II norovirus study...

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Yes. So it is in Q1 of 2023. This is a double-blinded placebo-controlled study with 100 subjects being challenged. So we won't have the data until the study is closed, assays are run and we've been unblinded. That's pretty much how it works.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Perfect. And another one for you still staying with norovirus. And the question is what about the elderly data? James.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Sure. So for norovirus, we looked at norovirus in the application of our construct, and I'll say that the more mature population, maybe not elderly, right? So 55 to 65 years of age and 65 up to 80 and taking a look at those with either different doses or placebo. It's a placebo-controlled study. We enrolled a total of 65 folks.

And what we saw in that study, I think we've released to the public to date, is that from an immunologic standpoint, alright, we saw the same immune response in an older population that we saw in our previous studies, done in subjects from 18 to 55 years of age. And that's very important as a clinician and a vaccine developer because we often have some concern about what we call immune senescence or immune response that's decreased in our more mature population. So the fact that using the same dose that seems to be very immunogenic in the previous populations, we again saw the same or similar immune response, a dose-dependent response, in our more mature people.

I think we mentioned that in our press release as well that the side effect profile is clean. And that goes really across the platform. It's very similar to placebo. We look forward to presenting data from that study once it's all amassed at international conferences and potentially publishing in peer-reviewed literature later this year if these articles are accepted in the journals, which I have hope that they will be.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, James. Very encouraging data. All right. We'll switch this one over Andrei. This one will be for you. And the question reads, do you feel time is running out or someone else would beat you to the finish in the space race before a viable product is ready to distribute prior to favorable conditions anticipating an investor interest goes elsewhere as it has been? I'm guessing this is COVID related, Andrei. You're on mute again, Andrei.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

I guess it's important to unmute myself when I have to answer. So okay, interesting question because I think investors see things very differently than, say, governments and regulators. So I'd like to make a distinction between investors and governments and regulators. Investors are much more short term oriented, particularly on the institutional side. So we've seen investor interest in COVID go up and down, probably now it's a bit down. But the story is very different as you talk to governments and regulators.

And what we are seeing actually is 3 reasons why governments are perhaps more interested in next-generation vaccines, in better vaccines, than they have been 2 years ago. So first of all, they've all gone through mass vaccination campaigns, and they've seen how painful, costly and lengthy they are, right? Nobody wants to do that anymore. Second, after Omicron, we've seen that first-generation vaccines have frankly failed us in a way, in many ways and so they have significant shortcomings.

And thirdly, because what COVID-19 has done to our lives, to the economies, we've seen that they are much more interested in thinking, okay, what about the next pandemic? Forget about COVID, how about disease X. So we've seen lots of interest in just better next-generation vaccines, and I think it's hard to argue that the pill vaccine is one of the best options.

And so -- the other thing I wanted to -- the other point I would like to make is that our offering is so distinctive that I don't see that need going away. It can address so many of the shortcomings of current generation injectable vaccines, but I just don't see that need going away anytime soon.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you, Andrei. So we're coming up close to the end of the hour. We'll take one more question. I know that we have some closing remarks by the team members as well. James, a question here on regulatory pathway. Specifically, what are your thoughts on regulatory pathway? I'm going to guess that, that's for COVID-19 vaccine.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Yes, I was just going to ask that. So I touched on this a little bit earlier, but when I look at regulatory pathways, I tend to look at both inside the United States as well as outside the United States. I go back to that COVID-19 challenge as a way to help inform and shape what would be our Phase III study could help us verify or validate immuno-correlates. And we could look at the impact our product has on boosting those who are already immunized, on looking at their immunogenicity, those immune correlates of looking at preliminary efficacy of sterilizing immunity and decrease in symptomatic disease and decreasing viral shedding as potentially a correlate for transmission.

So I think these are all very important questions that could be answered in part by that challenge. From COVID-19 standpoint, the SARS-CoV-2 virus continues to mutate, and we touched on that previously as well. I think the good preliminary information we have, knowing that we have an IgA mucosal response that's stickier, broader branching than what other vaccines may produce, allows us to potentially help out on whatever variance might arise. And that's differentiated from the current vaccines that are more serum IgG related.

Again, that's a very specific lock and key mechanism that works great when your vaccine matches up with what's circulating. But once it starts to slide through variation, the specificity of IgGs works against you.

We know that RNA viruses have a very weak editor, right? So a sloppy editor, you get more mutations and you get more variants. And we know that we expect between 3 to 4 times a year, a new variant to raise its head and sort of continue to go the course of spreading across the globe.

I go back to -- by the time you have built and developed your construct, you've tested it and you've gotten regulatory approval, you're 2 or 3 variants, if not more, behind the power curve, right? You're beaten before you ever get in the game. And I think us having a broader-based immunity could be something of great interest to regulatory authorities.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you, James. Thank you, not just for that answer, but for all the answers as well as Sean and Andrei, that was great, and thank you to all of our shareholders and audience members that sent so many interesting questions in.

We're going to move to some closing comments, and we'll start with Andrei. Andrei, if you could start, please. Thank you.

Cezar Andrei Floroiu - Vaxart, Inc. - CEO, President & Director

Yes, yes. Thank you. Thank you, Brant. So look, let me close by saying that I personally am here at Vaxart because I truly believe that we have the potential to transform the vaccine space to change how people think of vaccines, from how vaccines look like to how they are distributed to how they're administered. Imagine that we could make people forget that vaccines hurt. We can make them forget that vaccination centers existed. We could really free us all from what I call the tyranny of the needle, and that's big, right?

We have the opportunity to make a huge positive impact on health care globally. We could be getting more people vaccinated, both here in the U.S. and other developed countries where many people dislike vaccines, they are needle phobic, but also in the developing world where we could reach people in the most remote corners. And in doing so, we could save lives.

Imagine if you could get people vaccinated with just a glass of water and a pill, we could immunize more people faster, potentially offering them, as James and Sean alluded to, better broader protection. All of these being very important, particularly during pandemic. And the speed of vaccination -- I think James mentioned that, the speed of mass vaccination alone would be so important against fast mutating viruses such as COVID-19.

Now importantly, I believe that this opportunity that we have here at Vaxart is now bigger than ever. On one hand, the pandemic really highlighted the importance of vaccines, made us understand how important vaccines are. You may or may not know, but vaccines have been significantly underinvested before the pandemic, and I think that's changing. But on the other hand, the pandemic also showed us how difficult it is and slow and inefficient to vaccinate masses of people by needle. And so we at Vaxart can hopefully change all that.

Now finally and importantly, the Omicron wave has been very important because it made us so aware of the significant limitations of first-generation needle vaccines. For 2 years, we've been talking to people about these potential limitations, but back then they were potential, and so they were very conceptual to many people. Now they're very real. So I think lots of people now understand that we clearly need transformational innovation here. We just need better next-generation vaccines.

So I believe that we have the opportunity to write a little bit of history here to transform the vaccine space, to transform how we're fighting pandemics. Also, we have the opportunity to save lives, and you, our investors, can help us do that. Together, we can make a truly huge impact. Thank you so much, Brant.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Thank you. And Sean, I think you had some remarks.

Sean N. Tucker - Vaxart, Inc. - Senior VP & Chief Scientific Officer

Yes. Thanks, Andrei, for those great comments. I founded Vaxart more than 15 years ago in a loft -- because I wanted to change the way that people got vaccinated. And I continue to see the potential bar sign and our platform to make people healthier. Years ago, I thought about harnessing the advantage of mucosal immunity because it could be very critical in improving vaccine responses to pathogens, creating it at the actual sites of infection, places that injected vaccines can't reach because they don't really get mucosal surfaces. And there's a growing body of scientific

data from Vaxart and other leading immunology research that demonstrates that mucosal vaccines are really good at stimulating robust IgA responses compared to the injected vaccines while still stimulating a systemic response as well. We are obviously at Vaxart committed to exploring this value and the differentiating immune response.

Further, our approach may completely transformed the industry of administering vaccines. Think of how we deliver vaccines now from cold chain to syringes to red bag waste, and you realize that tablets could negate all these negative effects of the injected vaccine. As James pointed out before, in the developing world, the infrastructure to manage and distribute traditional injected vaccines doesn't really exist or doesn't exist very well. And for the developed world, we are always trying to improve, simplify and reduce both our cost to administer the vaccine, as well as reduce our waste footprint.

In addition, our technology has the potential to address another underappreciated vaccine-related challenge, which is the simple fact that vaccines can only provide protection when they're administered.

Moreover, current vaccine technologies create substantial barriers to adoption. Many people are afraid of needles. Many people just don't like to get an injection. Making vaccines easier to use will bring greater adoption and better herd immunity, and that's really what we want, not to make vaccines, to basically have immunity in people to stop pandemic.

With all this progress we've made to date and the data we've generated across multiple vaccine candidates, I'm confident our platform is technology sound and truly believe it's the most advanced mucosal vaccine platform. Certainly, there are several one-off indications of vaccines that are administered by a mucosal route, but I think we are truly, I believe, at least, that we are the most advanced vaccine mucosal platform, and we are trying to accelerate our development to take advantage of this platform technology.

I'm certainly very excited about all the discoveries we've made along the way. We have significant milestones coming up in 2022 and 2023. We have additional data to potentially demonstrate the world of vaccines is changing, and we're in a really good position to capture significant share of this multi-billion dollar market.

Society just came through 2 of the most trying years in our lifetime. In spite of all the headwinds we faced, the progress Vaxart has made really excites me. I mean, we've been doing some really important things, and I'm optimistic we can deliver for our shareholders on that vision when I first founded the company to really change the way the vaccines are administered.

I hope today we were able to explain why Proposal No. 2 is in the best interest of the company and shareholders and I really would like you to enable us to continue making our progress and vote in favor of Proposal No. 2 as well as all the other proposals for the Adjourn Shareholders' Meeting.

Brant Biehn - Vaxart, Inc. - SVP of Business Operations

Excellent. Thank you so much, Sean. James.

James F. Cummings - Vaxart, Inc. - Chief Medical Officer

Thanks, Brant. So let me just take a moment to share why I joined Vaxart. I think it was last September. I spent 26 years in the U.S. Army, serving as the Director of the Global Emerging Infectious Surveillance and Response System or GEIS at the Department of Defense. Looking at biosurveillance for over 71 countries, right? I was also a Director of Translational Medicine and regulated activities at the Walter Reed Army Institute of Research, and Consultant to the Surgeon General for all medical research and development. And in these roles, I saw a very real, impressing global need for improved vaccine technologies that were safe, effective and accessible.

I gained critical insights into the challenges of translating innovative technologies into vaccines that meet these global needs. My experience leading ICON GPHS, which is the federal business unit of ICON plc, the leading global contract research organization, and at Novavax have given me deeper insights in the practical and logistical needs of vaccines and vaccine development.

When I considered the opportunity to join the Vaxart team as Chief Medical Officer, I saw a game-changing technology and a passionate and expert team that's committed to transforming vaccines and global health at large.

In the 9 months I've been here, I've continued to be impressed with the focus and the dedication of our team, even in the face of the multiple challenges that you've heard about today. I'm proud of how the team has continued to adapt our COVID vaccine strategies in near real time as new viral variants and other challenges have developed. Essentially, building this ship while we're moving through rough and rapidly changing waters that is the COVID-19 pandemic. We all know we have work to do to realize the full potential of our vaccine candidates, and I want everyone online to know that everyone at Vaxart shows up each day focused on getting the job done. We bring our A game every day.

We need to execute as quickly as possible while still being very diligent to adhere to the stringent scientific and clinical standards. We own it. We'll have several opportunities in the months ahead to demonstrate the value of these efforts and I'm looking forward to that opportunity.

That said, we need your help. For those of you who have already voted as investors, thank you. Plainly said, voting to allow more shares gives me the tools I need to get this job done. For those of you who haven't voted yet, please do. For those who voted against Option 2, you have an opportunity to change your vote for these proposals. We need your support. These efforts demand it, and your teammates at Vaxart, we deserve it. This is an exciting time to be at Vaxart.

I'm really excited to be part of a team that shares my passion for vaccine innovation and for improving global health. And I want you there with me. We continue to look forward to sharing our progress with you in the months ahead, and I thank you for your continued support.