UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): **May 25, 2021**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-15771**	**83-0221517**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1330 Avenue of the Americas, 33rd Floor,
New York, NY 10019
(Address of principal executive offices) (Zip Code)

(646) 813-4712
(Registrant's telephone number, including area code)

N/A
(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 (see General Instruction A.2. below):

☐ 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, $0.01 par value	**ABEO**	**Nasdaq Capital Markets**

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 2.02. Results of Operations and Financial Condition.

On May 25, 2021, Abeona Therapeutics Inc. (the "Company") held a conference call to discuss its first quarter 2021 financial results and provide a business update. A copy of the transcript of the conference call is furnished with this Current Report on Form 8-K as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

The disclosure contained in Item 2.02 of this Current Report on Form 8-K is incorporated by reference into this Item 7.01.

The information furnished in Exhibit 99.1 hereto shall not be considered "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended, or under the Exchange Act, unless the Company expressly sets forth in such future filings that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**

99.1	Transcript of conference call held on May 25, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Abeona Therapeutics Inc.
(Registrant)

By: */s/ Brendan M. O'Malley*
Name: Brendan M. O'Malley
Title: Corporate Secretary

Date: May 26, 2021

Exhibit 99.1

Event Type: Q1 2021 Earnings Call

Date: 2021-05-25

Company: **Abeona Therapeutics, Inc.**

Ticker: ABEO

COMPANY PARTICIPANTS

Gregory W. Gin - Vice President-Investor Relations & Corporate Communications
Michael Amoroso - President & Chief Executive Officer
Edward G. Carr - Chief Accounting Officer & Principal Financial Officer
Juan Ruiz

OTHER PARTICIPANTS

Maury Raycroft - Analyst
Kristen Kluska - Analyst
Mani Foroohar - Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good day, ladies and gentlemen and welcome to the Abeona First Quarter Earnings Call. At this time, all participants are on a listen-only mode. We will open up the floor for questions and comments after the presentation. It is now my pleasure to turn the floor over to your host Gregory Gin, Vice President of investor Relations and Corporate Communications at Abeona. Please go ahead.

Gregory W. Gin

Thank you, Holly. Good morning, everyone, and welcome and thank you for joining us on our first quarter 2021 conference call. Press release announcing the first quarter results and recent operational progress is available on our website at www.abeonatherapeutics.com. On the call today with prepared remarks are Michael Amoroso, Chief Executive Officer of Abeona; and Ed Carr, Chief Accounting Officer. After the prepared remarks, we will host a Q&A session where we will be joined by Dr. Juan Ruiz, Vice President of Abeona who heads up Clinical Development for our MPS programs; and Dr. Brian Kevany, Lead Research Scientist working on our preclinical eye programs.

Before we start, I will review our Safe Harbor statement. Remarks made during today's call may contain

projections and forward-looking statements regarding future events. Forward-looking statements are made pursuant to the Safe Harbor provisions of the federal securities laws. These forward-looking statements are based on current expectations and are subject to change and actual results may differ materially from those expressed or implied in the forward-looking statements.

Various factors that could cause actual results to differ include, but are not limited to, those identified under the section entitled Risk Factors in the company's Annual Report on Form 10-K and quarterly reports on Form 10-Q filed by the company with the SEC. These documents are available on our website at www.abeonatherapeutics.com.

And with that said, I will now turn the call over to Michael. Michael?

Michael Amoroso

Thank you, Greg. Good morning to our investor community. We're excited to spend some time with you this morning. Thank you for joining us. As I approach the midpoint of my first 100 days in the job as CEO, I wanted to stop by reviewing three key strategic priorities for Abeona and our team.

First priority, being to bolster the relevant operational experience on our management team and board. Making sure we have the right coaches in place, the right experience to meet our goals going forward.

Second, delivering operational excellence, both timely and fiscally disciplined, to further advance our in-clinic programs toward meaningful milestones for patients in need.

And third, to further prioritize, execute, and advance our preclinical eye programs toward the clinic. We've made substantial progress on these priorities, and we're off to a fast start in 2021. I want to thank the team for their efforts.

First priority one, continuing forward under the right leadership. We continue to focus on building the right talent and experience on our team which positions us well to execute against operational goals. I'm very excited just this morning to have announced the appointment of Dr. Vishwas Seshadri, a Senior Vice President, and our new Head of Research and Clinical Development.

Vish, as he goes by, brings more than 20 years of experience across academia, followed by various senior and executive level leadership roles within the life sciences industry, overseeing product development, regulatory strategy and teams for submissions, and commercialization for novel therapies, including most recently, personalized autologous cell therapies in the CAR T space for Celgene and BMS.

Vish, has significant experience across early and late-stage development from first patient in all the way through successful commercial launches. He understands the tradeoff decisions and necessary discipline for evidence-based drug development.

Vish is also a proven coach in developing people across functions. Through his project leadership in working with clinical, regulatory, medical and commercial teams at Celgene, we're thrilled to have him join our team in early June and we look forward to introducing Vish to you on future quarterly calls. Welcome Vish to the Abeona team.

Also, in the first quarter, we have strengthened our Board of Directors with the appointment of four new independent members as well as myself. The new members have experience sitting on boards of public and private companies and bring relevant operational leadership experience within the life science industry, including areas such as clinical development, manufacturing of cell and gene therapy products, and corporate and financial compliance. The new members were selected based on their relevant and diverse experience, making them the right partners to the current management team in our pursuit of both near and long-term objectives.

I'd like to take a minute to review the new members and their critical experiences for Abeona. First, Dr. Leila Alland, a pediatric hematologist, oncologist and physician scientist. Leila spent over 20 years in the biopharmaceutical industry focusing on bringing novel therapies to patients with rare diseases, and is currently the Chief Medical Officer at PMV Pharmaceuticals. We're delighted to have Leila and she'll be partnering closely with Vish's team.

Next, Don Wuchterl. Having over 29 years of experience in the life science industry with senior roles in operations and CMC. Don is currently the Chief Manufacturing Officer at T-knife Therapeutics. He has significant experience building and leading CGMP manufacturing organizations and facilities so Don will provide essential feedback and guidance to our teams in Cleveland. Welcome, Don. We're really excited to have you.

Next is Faith Charles, a corporate transaction and security partner at Thompson Hine with over 30 years of legal experience and lead Thompson Hine's life science practice providing valuable insights to companies and capital markets, corporate governance, and strategic development such as M&A, licensing transactions, and strategic collaborations. Welcome to Faith.

And last but never least, Mark Alvino. Mark has provided leadership and experience in the areas of financial management and business strategy as a member of the Board of Directors of multiple life science companies including previously Abeona. Mark knows Abeona, our people, and our products well and his capital market experience will be invaluable as well as his longitudinal perspective on our organization. We're excited to have Mark back onboard.

Overall, I wanted to express my excitement to announce the addition of these respected leaders, experienced both to the management team and our board. I am confident that we have the right collective leadership in place that will help us to accomplish our objectives at this critical point in Abeona's lifecycle. Excuse me a moment.

Let me take an additional minute to comment on our board's aimed to enhance and evolve our governance. At our annual meeting of stockholders to be held tomorrow, our board recommends that stockholders vote for Proposal 2 to approve the amendment of our restated certificate of incorporation to declassify the board and eliminate three-year terms for directors in favor of one-year terms. Thus, further aligning with investor interests and increasing accountabilities of our directors to shareholders.

Our board believes that annual director elections are in keeping with sound corporate governance practices and promotes additional accountability to shareholders. If you have questions or need help voting for this very important proposal, please contact Greg Gin, our Head of Investor Relations.

Next, moving on to priority 2, advancing our clinical programs to our key milestones for patients. I'll start with an update on EB-101, our lead pivotal program for recessive dystrophic epidermolysis bullosa or as we refer to as RDEB. Regarding enrollment in EB-101 VITAL trial, we remain on track for activating a second study site in Northeast to complement Stanford on the West Coast in the second half of 2021. Patient physician interest in the study continues to be high and we're observing a greater willingness to travel on what we believe is the growing percentage of the population starting to receive vaccines for COVID-19.

Next, as discussed our last call, a fifth patient had been biopsied for the start of treatment. This patient's cells yielded product that didn't meet required release criteria as per the pivotal trial protocol. As a result, the clinical team and the patient had opted to re-biopsy and begin a new cell therapy product generation ongoing. We are hopeful to treat this patient in the coming weeks.

Also in parallel, additional patients have been identified and are being pre-screened to determine their eligibility for the VITAL trial entry criteria. As a reminder, the target for this pivotal trial is the treatment of approximately 35 large chronic wounds across 10 to 15 patients.

Next, the execution of our comparability plan is ongoing through our tech ops teams in Cleveland as well as ongoing communication with the FDA. Thus far in 2021 overall, progress for the EB-101 program has been significant and we continue toward our goal of completing enrollment in the VITAL study by year end. Thank you to the teams and our patients.

Let us next turned our attention to our adeno-associated virus, AAV-based gene therapy programs starting with our ABO-102 program in Sanfilippo Syndrome Type A or MPS IIIA. We are preparing for the FDA Type B meeting scheduled for next month in June. As a reminder, we plan to discuss the data to-date from the ABO-102 Transpher A study and next steps for a potential BLA path with the FDA.

We intend to discuss with the FDA whether the Transpher A data set could serve as the basis for BLA submission with natural history data as a viable control arm. We believe historical controls are critically important for MPS treatment and drug development globally in this disease as these children are being irreversibly impaired – irreversibly impaired and it's not feasible to give them a placebo.

We are excited and hopeful to review the data with the FDA at our upcoming meeting and partner on a viable plan forward for patients. Also, the FDA feedback from our upcoming meeting will continue to guide and enhance our development plans and pathway to marketing authorization in Europe as well.

Moving to our third in-clinic program EB-101, the Transpher B study in Sanfilippo Syndrome Type B or MPS IIIB. Product stability testing discussed in the last call for the clinical product from Nationwide Children's Hospital is now ongoing. To expedite timing, we brought some assay testing in-house. I want to thank our teams in Cleveland for their adaptability there.

After completion of stability testing, we'll assess our options forward for treating the additional patients remaining for Transpher B. During the first quarter in recent months, we also shared important clinical updates from both our Transpher A and Transpher B studies at multiple medical meetings and congresses. This is highlighted by positive data at the 17th Annual WORLDSymposium in February 2021, showing neurocognitive development of young MPS IIIA patients was preserved up to three years following treatment with ABO-102.

In addition, presented results from the Transpher B study continued to show signals of biologic effect with reduction in disease specific biomarkers in cerebrospinal fluid plasma and urine and reduction in liver volumes. We look forward to ongoing and additional updates of neurocognitive milestones.

Moving on to our third priority. Prioritizing and advancing our preclinical programs. We're focusing resources on ophthalmic indications within our AAV platform, following a strategic prioritization of our preclinical programs. On the back of our first AAV program success thus far in MPS, we're making significant progress toward adding new clinical programs to our pipe. We are conducting preclinical research with novel AAV capsid, including our wholly owned and partner capsids in six undisclosed eye indications.

To give an idea to our investor team, the estimated prevalence for each of the eye indications ranges from 5,000 to 15,000 patients in the US alone. This represents a significant market opportunity. And more importantly, more patient lives we can help. And this is – stays very true to leverage our identity as a fully integrated end-to-end gene therapy company for the highest unmet needs and patients.

During the first quarter, we presented the new data supporting the potential of Cre-mediated dual AAV vector technology to enable delivery of large genes targeted for treatment of Stargardt disease during an oral presentation at the Association for Research in Vision and Ophthalmology, otherwise known as ARVO 2021 Annual Meeting.

In addition, we also recently completed non-human primates studies comparing several capsids with AAV8, the current industry standard for intraocular administration.

I'm excited to say that the preclinical team delivered study results about four weeks early showing that AAV214 our novel capsid in-licensed from our AIM library was

superior to AAV8 using a recently developed novel route to ocular administration. In a separate non-human primate experiment, we tested our AAV214 and AAV214D5 two wholly- owned Abeona capsids versus AAV8 by sub-retinal dosing administration.

Both capsids demonstrated nearly identical levels of transduction compared with AAV8 of photoreceptor and retinal pigmented epithelium cells which are the cell types most frequently affected in inherited retinal diseases. We are very excited about the findings of these experiments which provide critical insight into the ability of our novel capsids to penetrate key cells and the optimal route of administration to accomplish this penetration.

These results position as well to move rapidly into the proof-of-concept studies in the second half of this year followed by toxicology studies in the first half of 2022. One of our lead scientists, Brian Kevany has joined us this morning and he could help us answer any questions we might have about some of this very significant preclinical progress.

With that I'll now turn the call over to Ed, our Chief Accounting Officer to review our financial progress thus far in 2021. Please, Ed.

Edward G. Carr

Thank you, Michael. I would like to remind everyone that the Form 10-Q is available on our website which is where you can get the details on our Q1 2021 financial results. In summary our cash, cash equivalents and short-term investments as of March 31, 2021, totaled $86.8 million compared to $95 million as of December 31, 2020.

For the first quarter of 2021, net cash used in operating activities was $13.6 million compared to $13.2 million for the first quarter of 2020. We believe we have sufficient cash resources to build on our momentum and fund our current development and operating plans through achieving a key anticipated milestones including multiple potential regulatory submissions.

And with that, I will now turn it over to the operator for Q&A.

QUESTION AND ANSWER SECTION

Operator

Ladies and gentlemen the floor is now open for questions. Your first question for today is coming from Maury Raycroft. Please announce your affiliations and pose your question.

Analyst: Maury Raycroft

Question – Maury Raycroft: Hi. Good morning, everyone. This is Maury Raycroft from Jefferies on the line. Thanks for taking my question. So, first question is on EB-101. I'm just wondering if you can find any more specifics into why the product didn't meet a release criteria for patient five? And I think you mentioned too that you're running a comparability program. Can you just remind me what the purpose of that is in half? And I guess what's the outcome of that? I think you mentioned comparability program and FDA but I missed a little bit of what you said in the middle there

Answer – Michael Amoroso: Sure, Maury. Good to hear your voice. It's Michael, I'll take that one. Yeah. So, patient five, we've got about 13 different release criteria that obviously the product goes through before we were able to send over and release for the surgical administration.

The patient's cells, as you remember, we grow the cells up and we used an enzymatic cleavage to take the sheet off and put it on our gauze with hema clips to deliver it to the OR. The protocol for pivotal states that the sheets can't even have any pinholes in the middle. That being said, while the surgical administration occurs we do make sutures in the product obviously to put these grafts onto patients. But the protocol with the FDA and agreement as of today unlike it was in the Phase 1/2 says you can't even have a pinhole in these sheets.

Keratinocytes are known to close – close over themselves within their borders to kind of cover these pinholes. So, this is something we're working on in the Phase 4 work but it is a pivotal trial. There is a stringent criteria, which we appreciate. So we had some holes in the products and small pinholes. And at that point in time what we decided to do was rather than yield lesser product to the OR, we decided to re-biopsy to try to give the patient the best ability to have a maximum delivery of transplanted area. So this is something that we, you know, with autologous therapy, cells grow a bit differently. We've seen this before and this is not something that's uncommon to us. But this is – this is why we decided to re-biopsy the patient.

To answer your comparability question, just a reminder, all of our product is made in-house. Our tech ops in Cleveland goes end-to-end. There's no CDMO dependency. However, right now as part of the ingredients for transduction, we use academic or Indiana retrovirus. Okay. And in order to have full control of our supply chain as we move to commercialization, the team in Cleveland has built our own retrovirus Abeona retrovirus.

So the comparability is a plan that was agreed upon with the FDA that within the pivotal, we will move from the first half of our patients that are made with product from Indiana retrovirus to the Abeona retrovirus. So while we're still treating patients clinically with the Indiana retrovirus ingredient, that's – it helps us transduce and make our keratinocyte sheets. At the same time we're doing analytical comparability to show that the similarity to the Abeona retrovirus and our final five patients will be dosed with the Abeona retrovirus-made product. So, that's why we have the comparability protocol, Maury.

Question – Maury Raycroft: Got it. Makes a lot of sense. And thanks for all the perspective there. Second question is just on the Transpher A Type B meeting with FDA in June. Just wondering if you could talk a little bit more about the plan going into the meeting, who's going to be attending with you, and also the disclosure from the meeting to I guess will you get minutes from that and when can we expect some sort of an update from that meeting.

Answer – Michael Amoroso: Yeah. Sure. So, Maury, I'm going to turn this question over – I'll give a quick highlight. I'm going to turn it over to my clinical lead of the program. Juan Ruiz is on the phone. But, you know, I think the key here is analyzing our pivotal endpoint, our data, and making sure that we that topic we've talked about before. Very important that natural history becomes – we think we've got the biggest data set here that natural history becomes a viable control arm, you know, for a path forward to a BLA. But, Juan, why don't you give a quick overview of what we look to accomplish objective-wise in the Type B meeting toward the end of June and some of the partners that will join us with the FDA.

Answer – Juan Ruiz: Yes. Thank you, Michael. Yeah. Thank you, Maury, for the questions. We have got previous meetings with the FDA and we have been implementing the outcomes of those recommendations from the FDA. But the main purpose of the meeting this June is to agree with the NDA on the way we propose to analyze the primary endpoint, the use of natural history study as a comparator group precisely to analyze the changes that we see in patients treated with ABO-102.

And also, what is the clinically meaningful difference that we propose in order to declare success on the program. Those are the main aspects that we are going to discuss in addition to the use of putting together different, the natural history of studies and testing different tools, we have the data to support that, and, yeah, discovery statistical analysis plan that we have provided. Those are mainly the aspect we want to discuss.

As I said, that had been previously discussed, implementing some of the recommendations, and provided the answer to pending questions.

Answer – Unidentified speaker: Thank you, Juan.

Question – Maury Raycroft: Got it. That's helpful. And so, could we expect an update potentially in July, August timeframe as to the outcome from the meeting?

Answer – Unidentified speaker: Yeah, Maury. I think, you know, on our next call, we'll definitely be talking about the results of our Type B meeting, that'll be an important path for us to communicate.

Question – Maury Raycroft: Okay. Okay. Thanks for taking my questions.

Answer – Unidentified speaker: Thank you.

Operator

Your next question is coming from Kristen Kluska. Please announce your affiliation, then pose your question.

Analyst: Kristen Kluska

Question – Kristen Kluska: Hi. Good morning. This is Kristen Kluska of Cantor Fitzgerald. I wanted to ask a question on EB-101. So, on the backs of some of the recent data you shared at SID, how are you thinking about the durability of EB-101 across the different wound type evaluated? And how important do you think this durability data is going to be for physicians and a sales team to promote in choosing a potential treatment option should multiple therapeutics become approved? And I know there's a lot of other factors to consider here, like wound type and size.
But I specifically wanted to hear your thoughts on durability.

Answer – Unidentified speaker: Yeah, Kristen. Nice to hear your voice. Thanks, I appreciate the question. So, you're making me smile, because I know we've talked a lot about this. So, yeah. I mean, I think you said it really, really well, right? So, couple of things. First of all, we're hoping, very much hoping that there'll be many, many options here over the next 5, 10 years for patients with RDEB. I mean, we've had nothing in this space for the last three to four decades and that's not given us the progress we need for these children and young adults.

The backbone of EB-101 is durability. That's the positioning of the product. The reality here is there is a small surgical administration like a graft and the product has to be worth it. And we believe it very much is. The focus of our product and our trial is in RDEB, the worst of the worst types of EB as well as the worst type of wounds about – we say about 50% of the wound burden of our RDEB patients at any given time is a more advanced wound. Large 20 centimeter squared or greater. We have some that are hundreds of centimeters, the entire backs for example and chronic. This being a very important point Kristen that you brought up different wounds.

Chronic is a wound that can no longer heal itself. Six months or longer it's been open. These are the wounds that patients suffer the greatest morbidity, pain, infection malnutrition, as well as lead to things like squamous cell carcinomas, you know, down the line. And these are the things that unfortunately lead to patients meeting their demise. So, we are focusing on what we believe is the worst of the worst wounds, about 50% of the wound burden on a patient at any given time.

Some of the other research going on today is very complementary. We truly don't believe there's a competition in this space. We need to be partnered for these patients that have no options. So, when you look at some of the other trials, for example, they're looking at other types of EB. Many of the trials are looking at small recurrent wounds. The way I describe it is the evolution of the wounds in RDEB start with small blister clusters. And ultimately. these wounds will evolve as the disease progresses and they become these larger chronic wounds.

So, Kristen you could see a world where we had two, three, four I hope 10 products approved over the 35 years of a patient's lifespan 30, 35 years a lot of times these patients meet their demise. They'll have experienced several therapies in the continuum of disease. But when the wound becomes truly problematic, the highest morbidity mortality these large wounds, they will need but we think is the biggest tool in the tool belt that will be EB-101 because they need long extended periods of covering these wounds.

And what we're hopeful for Kristen, as you know the vital trial looks at wound closure and pain improvement morbidity. Itch improvements so that you're not opening these wounds. But ultimately, we hope that as we collect this data and registries in time, if we close enough of these most problematic large chronic wounds, we hope that will change the prognosis of mortality for these patients.

So Kris, that gives you a little bit of an idea of the positioning of the product being durability, the wound it's specific for, and how it will complement other things being researched in the landscape today.

Question – Kristen Kluska: Thanks. And I know you've discussed the key differences between the recur and chronic wounds. But I wanted to ask if your researchers and your team are doing some more work to better understand when the best time to intervene with this treatment might be for some other recurrent wounds, excuse me, specifically just in light of the fact that the different patterns in terms of time to healing, time to re-blistering, et cetera, just to help with the greatest chance of success if commercialized?

Answer – Unidentified speaker: Yeah. It's an excellent question, Kristen. I think the question you ask here is what is earlier intervention? Why let these wounds get to this point, right? If we've got tools, what is the right time for intervention? So, we are and the scientific question hypothesis is out there, we are asking the question. We do plan on studying it in the future. Some of the things like I could talk about our Phase 4 work a lot.

Some of that Phase 4 work, I always call those practicality studies things, that are really important to add to our pivotal package, things like showing hey, a sheet with a pinhole can absolutely be transplanted and have the same durability, curative insights will close over. Things like getting patients out of the hospital faster because we know patients who have the right care at home, we want them to make sure they have that option so they don't have to stay in hospital.

Right now, they stay in the hospital just so a room nurse to make sure they're not laying on their engraftments. Things like, Kristen, where you just were, recurrent wounds. If we can treat the most problematic wounds, we have a lot of hypotheses that says, EB-101 would be able to do really well with recurrent wounds. We absolutely believe that but we'll look to prove that in the future. As you know, we're starting in RDEB, in large and chronic. But these are things that I call kind of our complementary Phase 4 work, work that you know bring Vishwas now as our Head of R&D will be really important that we start to continue to do the studies that matter to show this data.

Question – Kristen Kluska: Great. Thanks. And then on your prepared remarks you noted that some patients for the Phase 3 trial have been identified or in the prescreening process. Just wanted to make sure I understood that this is specifically referring to Stanford. And then I know you haven't identified the specific centers in the northeast, but could you talk about maybe you know more details like, is this a center that you would expect a lot of patient interest and have the investigators there potentially identified patients that they might want to go through the screening process?

Answer – Unidentified speaker: Yes, Kristen, you nailed it. That's exactly right. So, we've got some patients that are identified for Stanford but we also have started a bench for the Northeast site. And I don't mean to be coy guys, I'm just not announcing the site as per their IRBs until it's fully approved. I hope the next time we talk, I'll be able to do that. But a site in the Northeast is also screening and looking for some patients right now, patient charts, their care well there.

When you think about what that site would look like, what's an ideal site as we onboard. We've talked about with you in the past, you might remember, we'll probably come out of the gates with at least 10 sites when we commercialize. But when you think about the second study site, an important step in progress toward that. These are EB clinics, ongoing EB clinics. Why?

This is where we currently RDEB patients today. This is where you see the evolution of the disease of these patients when they need products like EB-101. This is where you have anesthesiologist, surgeons who understand how to give anesthesia to a patient who may have an esophageal stricture, the dilation procedures go on there, the hand, foot surgeries go on there.

So, you know, right now, these are academic type of centers who are specializing in EB, and they have the volume of the EB patients. That gives you an idea of what the profile of that Northeast site will be very similar to Stanford. And yes, when we talked about the additional patients being prescreened right now, we've got a few in the queue. We hope they meet eligibility criteria. That's out of Stanford. But our lead KOL out of the new site is also profiling some patient charts. So, once we have the site ready to move, we can go as fast as we can to get those patients into the trial and treated.

And what I'll remind you is our capacity out of Cleveland while we're in clinical stages. We could treat up to two patients per month. So, that's really, really important. And as we commercialize, we'll be making some configuration to our site. We'll be dedicating our first site solely to EB-101. And at that point, we'll be able to produce about 120 products in the first year moving to about 500 products if we have the demand in the second and third year. So, we've got the scale to be able to meet two sites ongoing, as well as getting ready for first year of commercial launch.

Question – Kristen Kluska: Great. Thanks so much for taking my questions.

Answer – Unidentified speaker: Of course. Thank you.

Operator

Your next question is coming from Mani Foroohar. Please announce your affiliation, then pose your question.

Analyst: Mani Foroohar

Question – Mani Foroohar: Hey. It's Mani Foroohar from SVB Leerink. Thanks for taking the call. the question. So, a lot of the focus obviously on the existing clinical opportunities. I want a little bit to the vector platform, and as you see, and how do you think about further opportunities in terms of EB raising further non-dilutive capital and partnerships using AIM vectors that you guys already own currently and as we think about that potential store value to the company.

Answer – Unidentified speaker: Hey, Mani. How are you doing? Thanks for the question. So, good question. And I think the key word for me that jumps out is optionality, right? We were a small cap. We've got the funding right now and the experience and the capital discipline. As Ed says that we believe we could take ourselves through our first clinical programs our in-clinic programs to literally regulatory milestones if need be. But at the same time, I've said this before, we're always looking for ways to bolster our either our capability, which I always think about as our timing to patient, our science and/or our financial opportunities, our financial runways, right?

That's, Mani, that's your question that's really important. Our financial runway is a reality that we think through every day and we try to be very surgical if you will in our approach. So, I think when you look at our profile if you think about the identity of the company and I love this question, I think our identity is an end to end fully integrated gene and cell therapy company. Cell therapy, of course, being within the umbrella of gene. Then that starts with an autologous program. But I think then you immediately see and that's why I think the MPS program is so important for human beings first and foremost. But also, so important to prove some muscle of our AAV platform our non-autologous gene therapy program.

And then, from there I think about the AIM capsid library and the follow on and how that's yielding some early excitement for us in the eye. And that's the way we're looking at it, Mani. It's a progression now that our identity as a gene therapy company that we are, you know, we look at the ability to produce for MPS product. The expansion of our facility will be able to produce for MPS in the eye. But I think we're very open to the right partners too. We realize that we're not going to be a jack of all trades and a master of none. We're going to look to specialize in our key area which today is gene therapy as well as ultra-rare diseases.

I like how we're pivoting from ultra-rare diseases. We're staying focused on maybe from ultra-rare to highest unmet needs whether it opens up bigger market opportunities. And if there's great partners in the upper arm in space or in the neurocog space for MPS, for three eye indications, or even in the germ space. I think we're always looking at those partners. I think that's something that's our responsibility to shareholders.

But hopefully me walking you through that a little bit is kind of how we see the evolution of our organization. And that we're fully dedicated to these initial milestones clinically as well as expediting the preclin. I think we've made really good progress on moving faster to get toward IND and these eye indications first prioritizing them and getting through the non-human primate experiments. We think that makes us – that much more attractive when we're sitting at the table to say, hey, we think we've got some leading science in these areas. And if the right partners involved then we could sit and have that conversation, too. So, that's how we're thinking about it, Mani.

Question – Mani Foroohar: Thanks. That's really helpful.

Answer – Michael Amoroso: Thank you.

Operator

I would now like to turn the floor back over to Michael for any closing remarks.

Well, thank you, operator. Thank you for the operative call. Thank you for Greg for setting it up and Ed and the team. Thank you to the Abeona team that's made really significant progress since I've been working with them in late last year. I want to always thank our patients and our families for having the faith and trust in us for their children or their loved ones, and we will stay committed.

Thank you to the investor community for your interest, your honesty, your questions. We'll continue to be transparent with you. We'll continue to update you on progress as we make those milestones. And if no other further questions, then I turn it over to you, operator to dismiss us today.

Thank you and look forward to chatting again soon.

Operator

Thank you, ladies and gentlemen. This does conclude today's conference call. You may disconnect your phone lines at this time and have a wonderful day. Thank you for your participation.