UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): November 11, 2021

THERAPEUTICSMD, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-00100**	**87-0233535**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

951 Yamato Road, Suite 220
Boca Raton, FL 33431
(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: **(561) 961-1900**

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, par value $0.001 per share	TXMD	The Nasdaq Stock Market LLC

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) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2).

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. ☐

EXPLANATORY NOTE

On November 12, 2021, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), filed a Current Report on Form 8-K (the “Original 8-K”) to announce that on November 11, 2021, the Company issued a press release, provided a slide presentation and held a webcast and conference call announcing its financial results for the third quarter ended September 30, 2021 (the “Earnings Call”). This Amendment No. 1 to the Original 8-K is being filed solely to furnish the transcript from the Earnings Call.

Item 2.02 Results of Operations and Financial Condition.

See information provided in Item 7.01.

Item 7.01 Regulation FD Disclosure.

On November 11, 2021, the Company issued a press release and provided a slide presentation, each of which were previously furnished with the Original 8-K. Also on November 11, 2021, the Company held the Earnings Call. A copy of the transcript from the Earnings Call is furnished as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01 and the information contained in Exhibit 99.1 is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in any such filing, regardless of any general incorporation language in the filing.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in its expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Index

Exhibit No.	Description
99.1	Transcript of Earnings Conference Call on November 11, 2021.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

SIGNATURES

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.

Date: November 16, 2021

THERAPEUTICSMD, INC.

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer

TherapeuticsMD (2021 Q3 Earnings)

November 11, 2021

Corporate Speakers:

- Lisa Wilson; TherapeuticsMD; Investor Relations
- Rob Finizio; TherapeuticsMD, Inc.; Co-Founder, CEO & Director
- Hugh O'Dowd; TherapeuticsMD, Inc.; President
- James D'Arecca; TherapeuticsMD, Inc.; CFO
- Mark Glickman; TherapeuticsMD, Inc.; Chief Business Officer

Participants:

- Louise Chen; Cantor Fitzgerald & Co.; Senior Research Analyst & MD
- Annabel Samimy; Stifel, Nicolaus & Company, Incorporated; MD
- Douglas Tsao; H.C. Wainwright & Co, LLC; MD & Senior Healthcare Analyst

PRESENTATION

Operator: Good morning, ladies and gentlemen. Thank you for joining us for the TherapeuticsMD Third Quarter 2021 Financial Results Conference Call. (Operator Instructions)

I would now like to turn the call over to Lisa Wilson, Investor Relations for TherapeuticsMD. Lisa?

Lisa Wilson: Thank you, operator. Good morning, everyone, and thank you for joining today to discuss our third quarter financial results and business update. This morning, TherapeuticsMD issued a press release announcing our third quarter financial results. The press release and accompanying presentation are available on the company's website, therapeuticsmd.com in the Investors and Media section.

On today's call from TherapeuticsMD are Chief Executive Officer, Rob Finizio; President, Hugh O'Dowd, Chief Financial Officer, James D'Arecca; and Chief Commercial Officer, Mark Glickman.

I would like to remind everyone that certain statements made during this conference call may be forward-looking statements. Such forward-looking statements are based upon current expectations, and there can be no assurance that the results contemplated in these statements will be realized. Actual results may differ materially from such statements due to a number of factors and risks, some of which are identified in our press release and our annual, quarterly and other reports filed with the SEC.

These forward-looking statements are based on information available to TherapeuticsMD today, and the company assumes no obligation to update these statements as circumstances change. An audio recording and webcast replay for today's conference call will also be available online in the Investors and Media section of the company's website.

For the benefit of those who may be listening to the replay or archived webcast, this call was held and recorded on November 11, 2021.

With that, I'll turn the call over to TherapeuticsMD's CEO, Rob Finizio.

Rob Finizio: Good morning, everyone, and thank you for joining our third quarter call. We look forward to updating you on the steady growth of our top line sales, but before going into further detail, I have an important announcement to make.

More than a year ago, I started a search for a company president who had the necessary financial and commercial expertise, the right personality and the right strategic vision of someone who would eventually be my successor as the new CEO of TherapeuticsMD. Back in August, after a comprehensive and exhaustive search process, we hired Hugh O'Dowd to fill the role as our President.

Hugh is a first-class professional with proven leadership and entrepreneurial skills and deep industry knowledge, having held leadership positions at both large and small pharmaceutical companies. The Board of Directors and I have worked closely with Hugh since August to ensure he developed an in-depth understanding of TherapeuticsMD. Now I'm happy to announce that the Board of Directors have unanimously elected Hugh O'Dowd as Chief Executive Officer and member of the Board of Directors on or before December 31, 2021.

After being at the helm of TherapeuticsMD since its inception 13 years ago, I will now transition to Vice Chairman of the Board of Directors and will now focus on Board-level strategic direction of the company. I'm confident in Hugh’s abilities to achieve our next milestone of EBITDA breakeven in the back half of 22 and building TherapeuticsMD into the premier women's health company in the United States.

With that being said, I'd like to congratulate you and ask Hugh to take over the call. Hugh?

Hugh O’Dowd: Thank you, Rob, and good morning, everyone. First, I wish to express my thanks and appreciation to Rob Finizio and our Board of Directors. Rob, this organization wants to thank you for your leadership in founding the company and launching a portfolio of 3 innovative and well-differentiated therapies.

TherapeuticsMD would not be where it is without your dedication, vision and leadership. I see enormous opportunity for the company and will invest all my energy in realizing our goal to become the premier women's health care company by serving our mission, empowering women of all ages through better health care.

By way of background, I was most recently CEO of Neon Therapeutics for 4 years, a clinical stage immuno-oncology company that was sold to BioNTech SE last year. Prior to this, I enjoyed a 20-year career in a variety of ascending senior leadership roles at Novartis, which included Country President, Region Head and Chief Commercial Officer

of the Oncology Hematology business unit, then the second largest oncology business in the world. I am deeply committed to our mission and serving women, an ambition, which has its roots reaching back 3 decades to my first launch as a marketer in the metastatic breast cancer setting.

My philosophy was shaped by these initial series of launch experiences, where great science must focus on clearly defined underserved patient populations in need of innovation. I look forward to sharpening this focus exclusively on women of all ages as we seek to improve their overall health. While serving our patient and health care professional communities remains my priority, it's also important that we deliver results to our shareholders, starting with achieving positive EBITDA in the second half of 2022.

We'll accomplish this by embracing financial discipline, which is why we are announcing today, a significant cost savings initiative that will reduce our annual costs in 2022 by at least $40 million. This figure does not include savings from or the costs associated with a potential divestiture of VitaCare estimated at approximately $20 million. In addition, we've already streamlined our senior leadership structure by eliminating 3 executive roles.

Last month, we announced the appointment of Mark Glickman, who will now be serving as our Chief Commercial Officer. Under Mark's organization, we now have a new head of sales, a new head of marketing and a new Head of Market Access. As you'll see in a few moments, this team has already produced results, and they are executing plans with a renewed focus on health care professionals. And finally, we are also actively working to address our capital structure to allow for more financial flexibility and ease the restrictive revenue and cash covenants that are currently in place.

In summary, I'm thrilled to be joining and leading TherapeuticsMD. My immediate priorities are: drive top line growth and overall operating performance. The elimination of at least $60 million of annual costs, including the successful divestiture of VitaCare, which we believe will then enable us to achieve EBITDA breakeven in the second half of 2022. And finally, to address our capital structure to ease the restrictive revenue and cash covenants currently in place. To maintain accountability, we will provide full year guidance starting in the first quarter of 2022.

I look forward to taking your questions at the end of the call. And now I'll turn it over to our Chief Financial Officer, James D’Arecca, to discuss our financial results in greater detail. James?

James D’Arecca: Thanks, Hugh, and good morning, everyone. Slide 6 shows a snapshot of our quarterly net product revenue trends, which continue to increase as we emerge from the COVID-19 pandemic. Our net product revenue for the third quarter was $24.5 million, of which $23.1 million was applicable toward our third quarter revenue covenant, which was successfully achieved. As compared to the third quarter of 2020, our net product revenue increased by 41%.

For ANNOVERA, net revenue increased by 84% as compared to the third quarter of 2020 to $11.8 million. This increase was driven by strong volume growth, partially offset by a slight decrease in net price as compared to the third quarter of 2020. Net price per unit of ANNOVERA remained stable as compared to the second quarter of 2021.

The volume increases for ANNOVERA this quarter reflected additional stocking in our wholesaler and pharmacy channels in advance of expected increased patient demand due to new insurance coverage beginning in the fourth quarter and our recently assigned J Code, which brings significant additional patient access in the public health sector. IMVEXXY net revenue increased by 17% as compared to the third quarter of 2020 to $8 million. This increase was mainly attributable to higher net pricing, partially offset by a moderate decrease in sales volumes shipped to customers.

Let me share some highlights from our financial statements on Slide 7. Our gross profit margin was 79% in the third quarter of 2021 and gross profit margins were negatively impacted by approximately $700,000 of BIJUVA export sales, which were recorded in the third quarter and were sold at cost. Total operating expenses of $60 million for the third quarter of 2021 included approximately $7.2 million of severance-related expenses attributable to the exit of 4 executives.

Absent these severance-related expenses, our total operating expenses were in line with our expectations as we continue to invest behind ANNOVERA and IMVEXXY. We expect our operating expenses to decrease in the fourth quarter to below $50 million, excluding the impact of any onetime costs related to our 2022 cost savings initiative.

Next year, as Hugh mentioned a moment ago, we expect to reduce our annual operating expenses by at least $60 million, assuming the divestiture of VitaCare. Net cash used in operating activities was $38.2 million for the third quarter. And as of September 30, 2021, we had $104.8 million in cash.

I'll now turn the call over to our new Chief Commercial Officer, Mark Glickman, to provide more detail around our commercial progress. Mark?

Mark Glickman: Thanks, James, and good morning, everyone. I'm excited to be on this call.

Before we delve into the company's commercial activities, I wanted to give you all a quick summary of my background. This is my 31st year in the health care industry. I started my career with large pharmaceutical companies before transitioning into the smaller, more entrepreneurial realm. As an executive with Kos Pharmaceutical, I helped the company grow from minimal revenue to over $1 billion in sales.

And at Auxilium, we increased our market cap from $900 million to a $3 billion sale to Endo in just 3 years. Most recently, our Chief Commercial Officer at Esperion Therapeutics where we introduced a novel cholesterol product directly into the global pandemic. You can see more details about my background on Slide 9.

Stepping into my role of Chief Commercial Officer. I contemplated the overall vision for TherapeuticsMD and saw 3 key factors that I believe will drive long-term success. First and foremost, our focus must remain on the patients and physicians. Second, an environment of accountability is crucial.

And this is something we've already implemented. This organization is focused on meeting the needs of our patients, physicians and our shareholders. Third, we've begun creating a performance-based organization to execute with excellence on our overall objectives. These moves are designed to help us achieve our ultimate goal to become the premier women's health care organization.

At TherapeuticsMD, we have 3 differentiated therapeutic options for women. Since joining and looking back, I saw an opportunity to address our overall commercial focus. Our approach, while appropriate during the pandemic has been adjusted, and we are now well on our way to transitioning to a health care practitioner prioritized effort.

After some internal changes, I believe we have the right people and the team is fully committed to the success of the company. With this refreshed commercial team in place, we have removed several barriers to launch and importantly, have seen significant wins with managed care, which we'll talk about in a few slides.

Based on the assessment I conducted, I determined we could improve sales by redirecting marketing programs. These programs are overweighted to the consumer and have now shifted to the health care provider. We also simplified the data orientation for the sales organization, which is designed to improve our ability to effectively execute. Finally, while we continue to have good managed care reach, we are redirecting our immediate focus to the opportunities where we believe we have the greatest impact as soon as possible.

Physician targeting became my first priority as we redistributed our activity to the highest decile prescribers. This effort, given the size of the rollout continues to progress in stages, while the evaluation of call and field activity is ongoing. As my second priority, we needed to refocus our sales representatives on solution selling. The key to the sales tactic is to make the salesperson the center of the solution process.

Most branded pharmaceutical products, despite great coverage, present some level of complexity regarding patient access. We have many great solutions to assist patients and physicians. I've asked our sales representatives to proactively discuss potential issues and align the appropriate solutions, ensuring patients receive our products at affordable prices.

Finally, we refined the focus to provide direction and tools that are designed to result in sustainable, consistent growth. I'm excited for the opportunities for success and recognize there's still much to do. I'm confident that with this refined focus and a reemphasis on accountability, we will be able to recognize the opportunities.

So what were the results so far during my tenure. First, the culture of accountability and close evaluation of performance resulted in an immediate increase in calls per day to targeted physicians, specifically those in the highest decile. Overall calls today have moved up from the low 8s to the low 9s. This is a critical gauge of effort. The next slide shows that these extra calls went to the correct targets. In September, 53% of our effort was through the top 4 deciles physicians who represent 40% of the market. This is the first time we've broken 50% and it was a 10% increase over August, which is great progress in only 1 month.

How does this impact prescriptions. On Slide 17, you'll see total monthly prescriptions for ANNOVERA, our long-lasting reversible contraceptive for women. To the left, in purple, are several quarters of relatively flat activity. In the June to July time frame, we implemented our changes in earnest, which accounts for the improvement beginning in August and really taking off in September. In September, we exceeded 3,000 monthly total prescriptions of ANNOVERA for the first time. On a quarterly basis, we saw an increase of over 1,000 prescriptions of ANNOVERA quarter-over-quarter or 14% jump, driven almost entirely by the success in September.

Slide 19 shows another indicator of our productivity in that cumulative prescribers increased over 8,100 for the quarter plus 1,300 new prescribers, most of which were in that higher decile area. This overall uptick is a result of the changes in our focus and our sales organization.

Turning now to IMVEXXY, which is an estrogen hormone therapy for postmenopausal patients suffering from VVA. We are very pleased with the IMVEXXY results because this quarter, while we prioritized ANNOVERA with the aforementioned HCP and targeting initiatives, we did not lose IMVEXXY traction. Currently, we're performing a full targeting and mix assessment, which should be completed by the end of the fourth quarter and fully implemented early next year. This will give us some of the insights we were able to achieve with ANNOVERA. As we move into 2022, we expect IMVEXXY to return to being a growth product for the company.

I want to stress that while we did transition most of our resources to a health care practitioner focus, we still enjoyed a very successful consumer campaign. The comedian and actress Whitney Cummins continues to be an outstanding spokesperson for us and her advocacy as an ANNOVERA user is influencing the right target audience. We also continue to see consumer appreciation and activities around the various IMVEXXY campaigns. We are encouraged by the benefits and the changes I discussed have already produced.

Looking forward, we believe there are additional accelerators not reflected in the slides I just showed. We have had significant managed care wins that will take place predominantly in the fourth quarter, and a J Code was recently assigned, which gives ANNOVERA access to a significant piece of the public health sector. We also filled the

22 vacancies in our field force with high-quality representatives who hit the field the first week in October.

We're entering into an exciting new phase for the company. I'm highly optimistic about TherapeuticsMD's future, and I look forward to speaking with you next quarter. And now, operator, please open up the call for questions.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) Our first question comes from the line of Louise Chen with Cantor Fitzgerald.

Louise Chen: Thank you for taking my questions here. So I have had a few that are coming in for me, and I wanted to ask you. So first question is why the CEO change now? I know you've been looking for a while. Is there any sort of inflection points that are driving your decision here? And then secondly, Hugh, what are you going to do differently from what Rob did, do you have a new strategic vision for the company?

And then just some housekeeping items in terms of the SG&A progression next year. Did you say that you'll be at less than $50 million of spend by the fourth quarter '21 and that will ramp down from there? And should we assume that you'll sell VitaCare next year and take out that $20 million as well or just kind of stick right now with the $40 million decrease in SG&A?

Hugh O'Dowd: So Louise, it's great to meet you. Let's unpack that because there's 3 good segments and questions. We'll start with Rob in a moment because I think that's helpful for context of why now and the considered process. Then I'll pick up and offer comment as it relates to the priorities, and then we'll finish up, I think with James as it relates to the VitaCare piece, in particular, but Rob?

Rob Finizio: Thanks, Hugh. Louise, thanks for the question. So as far as my role, so look, I remain fully committed to TXMD. I'm not going anywhere. I've changed my role to Vice Chairman and as Hugh takes over all operational accountability for TXMD, I'm going to focus on strategic Board level focuses.

And I have no plans currently to sell any of my stock or shares and am still probably one of the largest, if not the largest shareholder. So rest confidently that I am still fully committed here and still see a fantastic opportunity here. We did start this process over a year ago, right? And I met Hugh a full year ago, and we were looking for somebody with the right commercial background, the right financial discipline and really the right operating history, which we all found in Hugh.

And when we hired them as the President to ensure that he was as good as advertised, and that he could come in and operate the way we thought he could. And I'll tell you, he's met all of those criteria. And the Board has unanimously voted them in, and I'm really excited

for my next chapter here, and I'm really excited for Hugh. And I think we've got a winner, and I hope that answers your question. I'll turn it back to Hugh.

Hugh O'Dowd: Thank you, Rob. And by the way, it's a great kind of view. Louise, we really took the opportunity to emphasize what are the company's immediate priorities and why I really took an effort to emphasize the 4 points. Number one, we've got 3 tremendous well-differentiated assets and driving top line performance and growth is job 1.

And the operating performance surrounding that is where really our focus lies. It was important to align the cost structure with that top line evolution. And it was reasonable for us to consider how we should eliminate $60 million in full '22 cost structure, inclusive of the divestiture of VitaCare. And I think James could offer some additional comment there. But doing so, really does secure our pathway to EBITDA breakeven in the second half of '22.

That is a clear mission for this company. It's a clear mission with the Board of Directors, and I will see to it that we deliver. And then finally, how do we frankly do address our capital structure and these restrictive covenants that are in place? These 4 things are top priorities and are my focus. And beyond that, as I shared in the call. In Q1, we'll issue full year guidance. And I look forward to elucidate further beyond that period. But let me turn it over to James to your third query, Louise, as it related to VitaCare.

James D'Arecca: Yes. Thanks, Hugh. Yes, Louise, you had it right. in your initial question, we are expecting the SG&A to come down next quarter to below $50 million. And then when you think forward to 2022, you can take out at least the $40 million, which is the TXMD portion and then depending on the VitaCare sale and its timing, at least an additional $20 million.

So that would get you to a 2022 estimated SG&A spend. With regard to VitaCare, we do intend to divest it. That's our planning scenario right now. And as Hugh mentioned, we'll be back in the first quarter with guidance, but recognize that we're agile here and are thinking about all the different scenarios that are in front of us.

Louise Chen: Thank you.

Operator: Our next question comes from the line of Annabel Samimy with Stifel.

Annabel Samimy: A lot of change here. So congratulations on this new shift. I had several here. On -- I guess, my big question primarily is your first priority is driving top line performance. These products have now been in the marketplace for a couple of years, specifically IMVEXXY. Also, last quarter, you went from, I guess, going from a consumer focus. Now you're focusing again on HCPs.

But I guess my question here being that they've been around for some time, what does the HCP not know at this point about this product? Like what are the chances for inflection

because it seems like the managed care coverage was pretty solid, has been solid for a while. And so what is the physician community not getting about these products yet? A second question on cost savings. What exactly is being sacrificed from a cost savings perspective?

What should we expect? Is it DTC? Is it something else? If you can help us sort of frame that, please? And then on capital structure, alleviate the capital structure, what options do you have available to essentially adjust your balance sheet to give yourself some breathing room here?

Hugh O'Dowd: All right. Thank you for those queries, Annabel. Excellent questions. We're going to have Mark Glickman, our Chief Commercial Officer, answer the first piece. But one of the things I took note that I enjoyed in his presentation of a few moments ago, is that performance in the early shoots that we saw that, frankly, revealed growth is really driven by the inputs and changes that he's already erected comes in the absence of new items that are coming online now in the fourth quarter. And I think when we rebalance in a more open world post-COVID, we foresee a real opportunity to take advantage of those catalysts. Mark, would you care to elaborate?

Mark Glickman: Sure. Nice to talk to you again, Annabel. It's been a while. So regarding IMVEXXY and the health care practitioner focus, while your statement is correct, the HCPs know about IMVEXXY quite a bit. However, there's a lot of options out there for women and reminders and consistent communication and education about certain patient types, the reminder, the consistent reminder to the physician as to who is the proper IMVEXXY patient.

The physicians tend to forget, and especially throughout COVID, they'll tend to go towards generic products. They'll tend to go towards products that they used many years ago and IMVEXXY actually being fairly on the new side, we do need to continue that awareness. In fact, awareness is the #1 driver of prescribing of branded products in the industry. So it's not necessarily education, what are they going to learn new.

It's about the patient type, it's about continuing awareness and also making sure the entire office is aware how to prescribe IMVEXXY, what questions they may receive from the patients. So unlike ANNOVERA where there is more online interest for the postmenopausal women that are VVA sufferers, they do rely on their health care practitioner and we need to be there. We need to give them awareness, education, samples for the women.

All these things are critical. So I do think this is the most critical attention we can give right now to IMVEXXY. And we're rolling through a new targeting initiative to ensure that we're being as efficient and productive as possible with these new targets. I do anticipate to see this go back into a growth phase in Q1.

Hugh O'Dowd: Thank you, Mark. Now let's turn to your second query: is the nature and composition of these cost savings. So we've articulated from a '22 full year perspective,

savings of at least $60 million. Now $20 million of that is coming at least from the VitaCare divestiture. So let's park that off to the side.

So that means on what I'll call the TXMD pharma side of the business, there's $40 million coming from there. This is an exercise that is really driven by the shift that Mark has just elucidated. So we're really talking about rebalancing our focus, and lessened our intensity from the DTC media ad buy component of that. we believe while still leveraging that, as Mark noted in his opening remarks, but embracing the impact in power focus and execution of a greater health care professional focus, we acquire synergies.

And I think with that financial discipline, we can drive top line growth, we can drive EBITDA positivity and breakeven in the back end of next year. And I think that is just value creation that we can offer. Now as it relates to your third question, I'll turn to James to further go on.

James D'Arecca: Yes. So that was the one on the cap structure, I believe. I think the first domino that has to fall there is VitaCare. And we'd like to see first, what kind of proceeds are available in that regard. And then once we have that information, then I think it really kind of opens things up in terms of where we head next. You heard Hugh mention we want to address the revenue and cash covenants that we have in our current facility. So we'll certainly be looking at refinancing there. So -- but one thing at a time, let's take the first step, get to the VitaCare answer first, and then we'll take it from there.

Annabelle Samimy: Great – thank you.

Operator: (Operator Instructions) Our next question comes from the line of Douglas Tsao with HC Wainwright.

Douglas Tsao: Just maybe could you just walk through a little bit around the manufacturing change and the manufacturing disruptions for ANNOVERA? And how you are for supply into 4Q and 1Q?

Hugh O'Dowd: Doug, thank you for the question. Really, the current problem stems primarily from an extremely narrow FDA-approved release specification that requires us to reject batches that fall upside the release criteria for one specific test method. We have submitted an NDA supplement with FDA with a PDUFA date of December 12, 2021.

So that really provides data, we believe, justify a revision of that specific portion of the specification for that one test method. Now if the FDA approved the NDA supplement in December, we believe we'll be able to release batches that were outside the previously approved specification.

To be clear, this submission and potential approval by the FDA would have no impact on our product quality. We foresee a Q4 pathway that would permit satisfying increasing patient demand. But this is the first time that our ability to adequately meet ANNOVERA demand is in question due to the recent increase in batch failures.

Douglas Tsao: Okay. And then just as a second question, Mark mentioned accountability a lot. I was just wondering if you could just provide a little bit more of a sense of what he means by that?

Hugh O'Dowd: So Mark, would you care to elaborate?

Mark Glickman: Certainly, I mean accountability, when we think about the sales organization, to me, it's having a clear plan, a well-thought-out plan going into a quarter or into the year and executing against that plan.

So as we -- since I've been here and with my team, the new internal team working together, we're much more about giving direction where the representatives could be, where the right targets are and our expectation accountability is to follow call, follow messaging and follow overall accountability with solution selling.

And these are all really items that were not -- are not negotiable. So I don't want to comment about how things were before. But in my environment, everyone is accountable for the -- to execute against the plan as it's rolled out, and we're already seeing that.

So it's about activity metrics, it's about performance metrics, and it's about providing solutions as directed on a consistent basis. Additionally, internally, it's about having programs and plans that are ROI positive and being able to demonstrate that our spend is actually worthwhile and that our spend is actually going to benefit the overall organization, patients and physicians.

Hugh O'Dowd: Doug, I just want to say, I can't tell you how pleased I am with the early work done by Mark with our new Head of Sales, our new Head of Marketing, our new Head of Market Access, it's a new day. There is a vibrant energy associated with Mark's leadership, and I look forward to seeing continued results performing.

Douglas Tsao: That's really helpful. And then just one quick follow-up. Just in terms of the calls that are being made today, what percent are actually in-person calls versus ones that are virtual details?

Mark Glickman
: Thanks Doug. Great question. The statistics I put on the screen today are all in-person calls. So we're actually right now only counting in-person calls as a call. Offices have opened up, and we're out there. So the numbers I provided are all in-person office calls.

Douglas Tsao: Thank you so much. That's good to hear.

Operator: There are no further questions. I will now turn the call back to Hugh O'Dowd for closing remarks.

Hugh O’Dowd: Thank you, everyone, for a wonderful morning. We look forward to taking further follow-up. We wish you all a very good day. Take care and be well, and Happy Veterans Day.

Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for your participation, you may now disconnect.