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SCHEDULE 14A

**Proxy Statement Pursuant to Section 14(a) of the
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Filed by a Party other than the Registrant ☐

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- ☐ Definitive Additional Materials
- ☒ Soliciting Material Pursuant to §240.14a-12

LEV PHARMACEUTICALS, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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The following documents relating to the proposed merger between Lev Pharmaceuticals, Inc. (“Lev”) and ViroPharma Incorporated (“ViroPharma”) are attached:

1. Transcript from Investor Conference Call held on July 15, 2008

Additional Information About this Transaction

In connection with the proposed merger, ViroPharma will file with the SEC a Registration Statement on Form S-4 that will include a proxy statement of Lev that also constitutes a prospectus of ViroPharma. Lev will mail the proxy statement/prospectus to its stockholders. **Lev and ViroPharma urge investors and security holders to read the proxy statement/prospectus regarding the proposed merger when it becomes available because it will contain important information.**

You may obtain copies of all documents filed with the SEC regarding this transaction, free of charge, at the SEC’s website (www.sec.gov). You may also obtain these documents, free of charge, from Lev’s website (www.levpharma.com) under the tab “Investor Relations” and then under the heading “SEC Filings.” You may also obtain these documents, free of charge, from ViroPharma’s website (www.viropharma.com) under the tab “Investors” and then under the item “SEC Filings.”

Proxy Solicitation

Lev, ViroPharma and their respective directors, executive officers and certain other members of management and employees may be soliciting proxies from Lev’s stockholders in favor of the merger. Information regarding the persons who may, under the rules of the SEC, be considered participants in the solicitation of the Lev’s stockholders in connection with the proposed merger will be set forth in the proxy statement/prospectus when it is filed with the SEC. **You can find information about the Lev’s executive officers and directors in its definitive proxy statement filed with the SEC on April 16, 2008. You can find information about ViroPharma’s executive officers and directors in definitive proxy statement filed with the SEC on April 11, 2008.** You can obtain free copies of these documents from Lev by directing such request to Lev Pharmaceuticals, Inc., 675 Third Avenue, 22nd Floor, New York, New York 10017, Attention: Joshua D. Schein, Chief Executive Officer.

1. Transcript from Investor Conference Call held on July 15, 2008

FINAL TRANSCRIPT

Thomson StreetEvents™**Conference Call Transcript****VPHM—ViroPharma's acquisition of Lev Pharmaceuticals****Event Date/Time: Jul. 15. 2008 / 10:30AM ET****Thomson StreetEvents** www.streetevents.com[Contact Us](#)

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Jul. 15. 2008 / 10:30AM ET, VPHM - ViroPharma's acquisition of Lev Pharmaceuticals

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Colin Broom

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PRESENTATION

Operator

Thank you for holding, ladies and gentlemen, and welcome to the ViroPharma Teleconference Call. At this time, all lines are in a listen-only mode. There will be an opportunity to ask questions at the end of today's call, and instructions will be given at that time. Today's conference is being recorded, and thank you for your attention.

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I will now turn the call over to your host, Mr. Will Roberts.

Will Roberts - ViroPharma - VP, Corporate Communications

Good morning and welcome to ViroPharma's Conference Call and webcast to discuss ViroPharma's intent to acquire Lev Pharmaceuticals.

Certain statements regarding the timing of product approvals, regulatory filings and all elements of our financial outlook made during this conference call are forward-looking statements. As you know, forward-looking statements involve substantial risk and uncertainties and actual results may differ materially from those projected in such forward-looking statements.

The development, marketing and sale of pharmaceutical products are subject to risk and uncertainties and as a result, our actual results could differ materially from those results expressed in or implied by this conference call.

Please refer to the press release issued this morning and to our filings with the SEC for more information regarding the risks and uncertainties that could cause future results to differ materially from the expectations expressed in this conference call.

And with that, I'll turn the call over to Vincent Milano, ViroPharma's President and Chief Executive Officer. Vinny?

Vincent Milano - ViroPharma - President, CEO

Thank you, Will, and good morning to everyone on the call and webcast. With me today, in addition to Will are my teammates on ViroPharma's management team including Colin Broom, who is joining us from our European office, Bob Pietrusko, Tom Doyle and Dan Soland, our VP of Business Development, Clayton Fletcher, our Head of Medical Affairs in the US [Glen Tiletson], our Chief Accounting Officer, Rich Morris, our Head of PR and Advocacy [Christina Broadbelt] and our Manager of Investor Relations, Bob Doody. Also joining us this morning from Lev are Josh Schein, Lev Chief Executive Officer, and Jason Tuthill, its Director of Investor Relations.

This is certainly a thrilling call to be making, as after more than nine months of diligence and years of hard work looking for the right opportunity, we announced this morning our intent to acquire Lev Pharmaceuticals, and a New York-based biopharmaceutical company, focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases.

I will start this call off with some opening comments on the obvious fit with ViroPharma and on the deal itself. Then, turn the call over to Colin who will discuss in detail Lev's drug Cinryze, which we believe is nearing regulatory approval in the US and the dangerous inflammatory disease it treated called hereditary angioedema or HAE or C1 inhibitor deficiency.

Dan will follow with some commentary on Cinryze's positioning and some comments on the great unmet medical need we can meet with this impressive drug candidate. And then, I will come back for some concluding comments.

On slide five, as many of you know, ViroPharma has been extraordinarily active in the business development space and that we have very specific criteria that we keep in mind when assessing the strategic fit of any potential acquisition candidate. Lev represents an ideal strategic fit for our Company and our shareholders. Lev is a company with a late stage product opportunity in Cinryze. The product is the subject of a BLA, which is currently in the latter stages of review by the FDA.

Cinryze targets a serious, potentially deadly disease with a great unmet medical need. The disease, again, hereditary angioedema or HAE is a rare disease and an ultra-orphan medical opportunity addressable with a small sales force and as such, we would require modest additional infrastructure. Moreover, we note that C1 inhibitor depletion is also implicated in a number of other serious inflammatory disorders.

For Lev, this deal provides commercial and regulatory skills, expertise in infrastructure, and the capital required to optimize the launch of Cinryze and the deal itself provides Lev's shareholders with upside potential.

Based on where Lev is in their regulatory approval process with Cinryze, we believe that this product has a high probability of success for prophylaxis in the near term, and if FDA approves Cinryze, our focus will be on integration and successful launch into the US market. We look forward to bringing Lev's expertise in HAE into our organization and utilizing our regulatory and commercial experience to realize the full potential of the drug.

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Slide six. Cinryze itself, as Colin will describe in detail, is an important product opportunity that plays well with our strength. The drug is replacement therapy for patients with HAE, a therapy that is supported by over 35 years of effective use in Europe under the name Ceter.

We believe that Cinryze presents a strong exclusivity proposition through its work in drug designation in HAE. It is also the first and only C1 inhibitor replacement in development with data demonstrating that prophylactic therapy can significantly reduce the severity, duration and frequency of HAE attacks. The drug targets the underlying cause of the disease, which we believe will give healthcare professionals the opportunity for successful treatment outcomes.

In May of 2008, Cinryze went before an FDA advisory panel for a vote and emerged with a unanimous 21 to nothing vote in favor of approval for prophylaxis of HAE. Agency action is expected in the fourth quarter of this year and we believe there is a high probability of success in prophylaxis.

Although the BLA included data to support both acute and prophylactic use, the FDA panel was on prophylaxis only. There could be additional requirements for an acute indication to be approved. And although we are optimistic in the near term approvability of Cinryze, we should point out that the FDA issued a complete response letter to Lev that raised specific issues include CMC that need to be addressed. We evaluated the information in Lev's response to the complete response letter and are comfortable with their response. But of course, FDA still has to agree.

This is an important opportunity, not only could patients and families suffering from HAE have this preventative drug commercially available in the near term in the prophylactic setting, we also believe that it will drive additional near term value revenues, and cash flows for ViroPharma. Our primary focus out of the gate will be on integrating Lev into the business and successfully launching Cinryze into the HAE prophylactic market post approval.

Though the deal itself has a potential total value of \$617.5 million aggregate, the upfront consideration of \$443 million comprises \$356 million in cash and approximately \$87 million in ViroPharma stock, and it only values the prophylactic approval, as Cinryze's prophylactic data were the only data considered by the May FDA advisory panel and our emphasis is on the prophylactic market.

However, we have built in to the deal two contingent value rights to allow Lev's shareholders to participate an additional potential upside. The first contingent payment would be an additional \$0.50 a share, or \$87 million in cash and it would be payable if FDA approves and grants orphan exclusivity for Cinryze for the acute treatment of HAE.

If that condition is not met, the first contingent payment could still be earned if no other C1 inhibitor drug receives orphan exclusivity for two years post approval of prophylaxis. The second contingent payment of equal value to the first is payable when Cinryze achieves at least \$600 million in cumulative net sales. In order to ensure that Lev has appropriate operating capital to enhance the likelihood of a successful launch, we also purchased \$20 million of Lev common stock.

This deal structure was designed to be a win/win, with an upfront payment that considers a prophylactic approval and contingent upside that would be suggestive of a very successful product and would represent payments we would be happy to make.

We intend to provide specific product guidance once the product is approved. However, for now we can share with you that we believe Cinryze to be at least a \$250 million to \$350 million products per year at peak with margins of between 65% and 70%.

With that, I will turn the call over to Colin Broom, ViroPharma's Chief Scientific Officer. Colin?

Colin Broom - ViroPharma - VP, Chief Scientific Officer

Thanks, Vin, and good morning to you all. I share Vin's excitement with this acquisition. I've spent many hours and days over the past several months on the HAE opportunity and I am convinced that Cinryze is an important drug that will save many lives and just as important, it will improve many lives and will be a significant acquisition for ViroPharma.

So, let me start with slide nine for those of you who are following along and walk you through the regulatory history of Cinryze, Lev's replacement therapy for C1 esterase inhibited deficiency. First, in 2004, Lev received orphan drug designation in HAE providing the potential for seven years of market exclusivity at launch.

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In 2005, Lev received first track designation for Cinryze from the FDA. And in 2007, the Phase 3 data from both the prophylactic and acute studies were presented. Importantly, while there are several interesting drugs currently under evaluation in the acute HAE treatment setting, Cinryze is the only drug in development today with pivotal prophylactic data and a BLA that has undergone priority review.

In July 2007, the Cinryze BLA was submitted for both acute and prophylactic treatment. In January of 2008, Lev received their complete response letter regarding their BLA for both the acute and prophylactic indication. And in April 2008, Lev filed their complete response to their type two letter, received in January, which has been accepted for review by FDA. October the 14th is the targeted action date.

We've reviewed closely the response to FDA and are confident that they have adequately addressed all of the issues outlined from the original complete response letter. In May of 2008, FDA's Blood Products Advisory Committee voted unanimously 21 to zero for approval of Cinryze prophylaxis. The acute data were not considered at that panel.

Lev has also received specific feedback from the FDA's Office of Orphan Drugs that they will grant orphan exclusivity consistent with the label and by indication. Meaning, they intend to consider prophylaxis and acute treatment as two different orphan indications.

At this point, based on the panel vote in May and the work that has occurred since, both ViroPharma and Lev believe in the potential for US approval to occur in the near term or HAE prophylaxis. We believe that this is the largest HAE market opportunity though with additional work — additional upside from an acute treatment approval is certainly possible.

Now, let's move to slide 10 and talk about the HAE in more detail. HAE is a life-threatening and debilitating genetic disorder caused by a deficiency of C1 esterase inhibitor protein, which is involved in regulating the inflammatory process.

HAE is an autosomal dominantly inherited disease. That means that children of one parent with HAE will have a 50% chance of having that disorder as well. So, it sadly effects not just one member of the family but often two or more.

The typical patient takes nine years to receive appropriate diagnosis. Patients may present with symptoms as early as two years of age, or even younger, though often these symptoms go unrecognized and patients end up in the emergency room with a severe attack before they're diagnosed. On average, attacks last up to three days and occur once a month, impacting work, school, social outings, and all other aspects of life.

The most severely affected patients may have two to three attacks per week and unfortunately, up to 40% of patients eventually die from an HAE attack, usually the most severe laryngeal form before the attack can be correctly identified and then treated in an emergency room setting.

Current literature and models suggests there are approximately 10,000 people in the US who have this deficiency. Though thus far, only approximately 4,600 have been diagnosed and are being actively monitored and treated. Better treatment options, however, will always drive better diagnosis and patient identification.

The current treatment in the US, primarily [Denizol], an anabolic steroid, is simply inadequate. Anabolic steroids do not treat the attacks, nor the underlying cause of the condition and the side effects of such steroid use are significant, including liver toxicity, lipid abnormalities, carcinogenicity and viralization. So, they are dangerous. Particularly for longer term use and tend to be underutilized in general and, as you would expect, usage is particularly limited among women and children. Nonetheless, because of a potential for a severe laryngeal attack, many people today choose prophylaxis with anabolic steroids.

Cinryze represents a simple product proposition. It is a replacement therapy for patients with this C1 esterase inhibitor protein deficiency, targeting the underlying cause of the disease. To give patients the potential for proven safe and reliable prevention.

Slide 11 depicts how C1 inhibitor deficiency, HAE, can manifest in many different parts of the body. The most dangerous and complex manifestation is a laryngeal attack, which may lead to death from asphyxiation and often requires intubation and tracheotomy. Abdominal attacks are associated with severe pain and intestinal obstruction, with vomiting and dehydration and leads to hospitalization and often unnecessary surgeries. Nearly all body systems can be affected, but the most common presentation is in the extremities where swelling of the hands and feet is functionally disabling.

However, a major problem to patients and physicians is that there is no way to tell whether patients attack is mild or severe or whether a patient is predisposed to a less complicated extremity attack versus a deadly laryngeal attack. The next attack could always be significant, thus the need for prophylaxis in many patients and round the clock vigilance among these patients and their families.

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You'll see on slide 12 a photographic example of a facial and dangerous laryngeal attack and these patients can progress to this grave condition from being unaffected in a very short time, a few hours.

Moving to slide 13, what is a C1 esterase inhibitor? Well, it's the human plasma protein that regulates the inflammatory process. But thankfully, most people have no problems synthesizing this protein. C1 inhibitor is the main regulator of the early activation steps in a number of interrelated biochemical pathways including the contact, the complement, and the fibrinolytic systems that lead to the release of [tied ends] and other inflammatory mediators.

When these systems are activated and remain unchecked by inhibitor, HAE patients experience the inflammation typical of an HAE attack. So, this is a critical protein, it is required to keep these systems in check. Unfortunately, a person born with a genetic ability to synthesize enough C1 inhibitor is prone to HAE's landmarks — hallmarks, disfiguring swelling, debilitating pain, and in the most severe cases, asphyxiation and death.

Cinryze is C1 inhibitor replacement therapy for these patients by adding back C1 esterase inhibitor, Cinryze inflammatory pathways are kept in check and the serious clinical manifestations of HAE are treated or ideally prevented all together.

Now, as I mentioned earlier, patients today with this deficiency have far too few choices for prevention or treatment of acute attacks. And the choices that exist are limited and suboptimal. As I summarize on slide 14, for US patients seeking prophylaxis against HAE to prevent their attacks all together, their only choice today are anabolic steroids. Again, the side effects are significant and their use therefore, is limited.

In Europe, patients have more choices for prophylaxis, there steroids are used but also C1 inhibitor replacement therapy similar to Cinryze is available. This is another choice in Europe and the choice we will bring to US patients with Cinryze, the only drug in development with orphan drug designation for and pivotal clinical data in prophylaxis of patients with HAE.

On slide 15, okay? I show that HAE attacks are always significant and they can be fatal. And unfortunately for patients, the disease manifestation is variable, so there's no way for a patient to tell which attacks will be moderate or which may result in a deadly laryngeal attack. Nor is there a way to tell how long it will take for an attack to progress. Meaning every patient is at risk of a life threatening attack and C1 inhibitor is used up more quickly in patients during an acute attack, leading to a further increase in the severity and duration of an attack.

These are a few of the reasons that selective prophylaxis is an essential consideration for these patients. Even though there are limitations with anabolic steroids, this is the only prophylactic choice a US patient has today.

We also know, through Lev's market research of over half of polled US HAE patients, claim that their needs are not being met by the current drugs. Dan will go into further detail in a moment. Again, there is a great medical need for prophylactic C1 inhibitor replacement.

Moving on to slide 16, let's now discuss the pivotal prophylaxis data on which Lev has submitted for approval here in the US. There are — these are the data that were considered by the May 2008 FDA advisement panel. This was a randomized, double blind placebo controlled multi-center study in 22 subjects with a history of at least two attacks per month. The study met its primary endpoint with statistical significance, mainly reduction in the number of HAE attacks.

Patients in the Cinryze arm had a 52% reduction in the total number of attacks, the P value less than 0.001 (sic—see Presentation Slides) and not surprisingly, patients in the placebo arm received significantly more orphan label Cinryze than patients in the treatment arm.

The study also met its secondary endpoints. Patients receiving Cinryze had a 66% reduction in days of swelling, decreases in average duration and severity of attacks, all demonstrated with a high level of statistical significance. 19 of 22 patients or 86% showed improvement in the Cinryze arm and 11 of 22 patients or 50% had no swelling or minor swelling.

To date, over 7,000 doses of Cinryze have been administered with no immunogenicity and no reports of drug-related serious adverse events. This is consistent with the experience in Europe, where C1 inhibitors have been on the market and well tolerated for 35 years.

Finally, on slide 17, Lev also has open label studies ongoing today with C1 inhibitor replacement therapy with over 100 patients receiving drug and with more on the waiting list. All of these patients will be converted immediately on approval to commercial product and will provide a base of revenue out of the gate.

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So, we have a great opportunity with Cinryze ahead of us. If FDA approves the drug, we expect to launch a very important drug this year and we believe will save and improve many lives. And further, we have some very interesting opportunities outside of HAE that may be addressable with C1 inhibitor replacement therapy.

With that, I will turn the call over to Dan for some comments on the commercial plan. Dan?

Dan Soland - ViroPharma - VP, COO

Thank you, Colin, and if you would please take a look at slide 18, I want to take a few minutes to talk about some of the important information that we know through Lev's extensive market research and to touch on the commercial launch plan from a very high level of course.

Let's start with slide 19. Overall, these promising times for patients suffering from HAE, there are several promising drugs in development today, all of which have orphan drug designation. However, because of the significant differences between patients who need treatment and those who need preventative therapy, the FDA has indicated that they will consider HAE prophylaxis and acute treatment as two different orphan indications and that orphan drug approvals would be granted based on their label indication. So, there are two orphan drug approval tracks for this disorder. This is important, because there is only one drug among them with prophylactic data and that drug is Cinryze.

These are the data that were considered in the May FDA advisory panel who voted unanimously in favor of the approval. There are also a handful of promising drugs in development for acute treatment of HAE. Cinryze is one of them. CLS Behrings Berinet, another C1 inhibitor drug has acute data, but no prophylactic data. And Jerini's Icatibant and Dyax's DX-88 also are targeting the acute market, but have too short a plasma half life to be considered for prophylaxis.

So we believe that for this, and many other reasons, Cinryze is very well positioned in the HAE prophylaxis compared to other drugs in development in this space.

Now on slide 20, the HAE market itself is likely under diagnosed. While according to the US Hereditary Angioedema Association, there are approximately 4,600 patients in the US currently diagnosed with a C1 inhibitor deficiency. The overall market, including undiagnosed patients, is likely to be over 10,000.

Approximately 1,500 of these patients are currently prophylaxed with an anabolic steroid despite its significant limitations and according to primary research, are anxious — patients are anxious for a better prevention option. So, assuming 1.5 prophylactic doses per week, this represents nearly 117,000 prophylactic treatments per year currently, representing what we believe to be a multi-hundred million dollar market opportunity with a comparable price to other ultra-orphan drugs.

More important than the size is the major unmet medical need. These patients are very sick and HAE impacts their lives in many ways. They're in desperate need of a better drug option to prevent their potential, deadly HAE attacks all together and we believe strongly that Cinryze will satisfy this need.

Now, on slide 21, the topic of ultra-orphan drugs is one that many of you may be familiar with. Orphan drugs, a regulatory term, are drugs that address diseases with a prevalence of 200,000 or less in the United States. The term ultra-orphan, on the other hand, is not a regulatory term, but rather it's jargon for an orphan drug that addresses a very rare disease with a far smaller prevalence than a typical orphan drug.

There are several well-known, effective and successful drugs on the market for various ultra-orphan diseases today. It includes Genzyme's Cerezyme for Gaucher's disease, Genzyme's Fabrazyme for Fabry's disease, Shire's Elaprase for Hunter's syndrome and Alexion's Soliris for PNH, a disease affecting only about one or two patients per million.

All of these are important drugs for rare, but life-threatening diseases. We believe that Cinryze, which will treat a disease affecting between one in 10,000 and one in 50,000 patients will be the next of these important ultra-orphan drugs.

So, now if we go to slide 22. Much is already known about the HAE landscape thanks to the Lev commercial team's significant market research on the HAE marketplace. Among the findings, market research that found that there are more than 700 allergists responded that they treat at least one HAE patient today. In total, 700 allergists are seeing more than 3,500 patients on a regular basis and a subset of these 700 allergists, a subset of 175 of these docs are managing 70% of those 3,500 patients. Among the families of an HAE patient, only 30% — 34% of other family members have been tested for HAE and this is despite the 50/50 chance that a parent with HAE will pass it on to their child.

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Much of our focus, and Lev's focus to date, has been on disease awareness. It is also essential that we increase the level of testing in these families to ensure that all patients with HAE are diagnosed and we have — and all have access to drugs that will prevent dangerous and deadly attacks.

So, as we move on to slide 23, up to 75% of these allergists mentioned, which will be the primary target for our sales effort, currently use methods with steroids, despite the limitations that Colin discussed earlier. Lev's market research showed that these doctors are largely unsatisfied with their current prophylactic option. Nearly 60% of the responding allergists rated their current satisfaction level low.

Further, when asked which patients they would convert to a C1 inhibitor replacement therapy and why, these allergists said that they would convert more than 60% of their patients with two or more attacks per month and that they would convert approximately 80% of their patients if they experienced four or more attacks per month. These data suggest a very high level of dissatisfaction with current treatment options and a great deal of interest in a drug like Cinryze.

So, as we move on to slide 24, Lev's market research also demonstrates a lack of satisfaction among HAE patients. Approximately 66% of patients taking steroids despite the fact that they are concerned about associated long-term health problems. They also indicated, during the market assessment work, a strong preference to convert from an anabolic steroid to a C1 inhibitor therapy. They view prophylaxis as a necessary option for return to a normal life, despite the fact that their prevention needs are currently, largely unmet.

Slide 25, without going into too many details about the commercial plans, for obvious reasons, the Lev commercial team has done an excellent job of getting a great plan in place for launch. Their pre-launch work has been exceptional in preparing the market for Cinryze. Also, if the FDA approves Cinryze, at the time of launch, there will be a robust patient assistance program in place to assure that all appropriate patients can get this potentially lifesaving drug.

In addition, for us, as Vin already mentioned, one of the elements that makes this target fit perfectly with ViroPharma is that it will require minimal additional infrastructure to launch this product. Obviously, we will want to retain the knowledge that Lev has. We will also add a small number to the organization to support the drug, including a sales force of approximately 20 people.

On to slide 26, we are optimistic in the near term approvability of Cinryze in the prophylactic setting. Though our focus will be on integration and launching the drug for prevention of HAE attacks, the acute opportunity presents the potential for additional upside, but there is more work to be done.

We may also consider other indications and usage and the potential for this drug in other territories. So, we have many means of growing this drug throughout its time of market exclusivity at our disposal and the capital and experience to make it happen.

As I already mentioned, I applaud the strong work of the Lev team in getting this far. Their work along with our commercial expertise and infrastructure will help support a strong launch. This is a great opportunity for Lev and their shareholders, not only do they participate in any upside for the product, Cinryze will have the backing of our strong capital position, our regulatory team, financial and commercial infrastructure, and experience to assure that this opportunity is maximized.

With that, I'd like to turn the call back over to Vin for closing comments.

Vincent Milano - ViroPharma - President, CEO

Thank you, Dan. For those following the slides, you should now be on slide 28.

So in conclusion, our acquisition of Lev Pharmaceuticals represents an ideal, strategic fit for ViroPharma. This presents an opportunity for us to acquire another near-term and life-saving drug opportunity that we believe will address a significant medical need.

The fit in the ViroPharma is clear. Cinryze is a niche market opportunity, addressable with modest additional infrastructure and by our analysis, has a high likelihood of near-term approval. Integration is doable, with little, if any distraction from our other important endeavors in the CMV — and C deficile markets and both companies will be fully engaged.

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Lev has developed great expertise in the HAE C1 esterase inhibitor arena and these are strengths that we will seek to retain. Lev and their shareholders gain exceptional regulatory experience, the wisdom of an experienced commercial team and an infrastructure already in place to optimize the launch and assure that this product is available for all patients who need it. And importantly, we will have strong and growing cash reserves thanks to Vancocin's continued performance.

Thank you for your time this morning. I assure you that we will remain as communicative as possible as we head into and through the acquisition of Lev. We look forward to doing great things together for HAE patients and shareholders alike.

As a reminder, in the room with me for Q&A are Colin, Dan, Bob, Tom, Glen, Will, Christina and Bob Doody, and we also have Josh and Jason from Lev with us as well. Operator, are there any questions?

QUESTION AND ANSWER**Operator**

Yes, we do have a few questions. The first question is from Thomas Wei from Piper Jaffray. Please ask your question.

Thomas Wei - Piper Jaffray - Analyst

Thanks very much. I had a question just — when you're sizing up this market opportunity, \$250 million to \$300 million, it looks like you're going after a target population of the 1,500 who are on steroid prophylaxis, but then, it sounds like there's separate market research here looking at patients with two plus attacks per month or four plus attacks per month. Can you give us a sense of the diagnosed patients in the US, how many would fall into each of those categories on a number of attacks per month basis?

Dan Soland - ViroPharma - VP, COO

Thomas, it's a very good question and I don't have that level of data available to me. What we can say is of the 4,600 patients who are diagnosed with HAE, we know that at least 1,500 of those are currently on some level of prophylaxis with an anabolic steroid, with all the limitations of anabolic steroids and we also have a strong belief that of those 1,500 patients who are on anabolic steroids, most of those are probably males and most are probably adults. So again, we think there's a tremendous opportunity for the Cinryze product. With its efficacy and its safety, not only for men but for women and children.

Thomas Wei - Piper Jaffray - Analyst

But presumably because it's an oral drug, should we think of the target population with either these two or four plus attacks per month as being a subset of those who are on steroid prophylaxis, can you give us any indication of how big that very severe part of the market is and might be willing to go in for a twice a week infusion?

Dan Soland - ViroPharma - VP, COO

Okay, so maybe there was a bit of confusion, but Cinryze is an IV drug. Were you suggesting that it was oral, Thomas?

Thomas Wei - Piper Jaffray - Analyst

No, no, no. I'm saying that should we think of you know — if 1,500 patients are taking oral prophylaxis right now with steroids, should we think of the IV prophylaxis market as really some subset of that and that you really would only be able to capture some small proportion?

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Dan Soland - ViroPharma - VP, COO

No, I think that it's bigger than that, Thomas. I think that what we would suggest, because of the limitations with anabolic steroids that the 1,500 patients who are on an anabolic steroid, that if you had a safer product that the market opportunity would be larger than 1,500.

Unidentified Company Representative

I think, Thomas, in addition, remember that it's not just the number of attacks, it's also the quality of life issues that these patients suffer from.

Thomas Wei - Piper Jaffray - Analyst

Okay, maybe from a different angle here. It sounds like these C1 inhibitors are available in Europe, can you give us a sense there what the penetration is into the prophylactic usage, what exactly are the sales of these drugs in Europe?

Unidentified Company Representative

Josh?

Josh Schein - Lev Pharmaceuticals - CEO

Yes, there are currently two manufacturers in Europe, our partner the Sanguin Blood Supply Foundation that currently makes their C1 inhibitor product, Ceter, available, mainly the Netherlands though to an extent in Belgium and Finland as well and they don't — they don't break out their numbers for their C1 inhibitor, nor does the other manufacturer, CSL.

So, it's a — it's tough for us to give you any guidance there. I will say, that historically the use in Europe has been primarily on the acute side, though there's been an increasing appreciation for the prophylactic application and that, as you've heard today, it's really the thrust of the commercialization effort. Here in the US, we do see that as the much bigger commercial opportunity here.

Thomas Wei - Piper Jaffray - Analyst

I'm sorry, I'll jump back in the queue, I promise, but was that a lack of prophylactic data that caused the Europeans not to use it that way — what is so different about the US experience that makes you confident that you're going to get a lot of prophylactic use if it's not used that way in Europe?

Josh Schein - Lev Pharmaceuticals - CEO

Well, that's based on our own market research here in the US, but you're correct in that no rigorous clinical trial — placebo-controlled clinical trial had been done for prophylaxis in Europe. And so, that certainly limits its acceptance there. But as you saw in this presentation, our prophylactic data looks extremely strong and we have been talking to both patients and physicians for a number of years now and we do see a very strong interest in prophylaxis here in the US.

Thomas Wei - Piper Jaffray - Analyst

Thank you.

Unidentified Company Representative

Thank you, Thomas.

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Operator

Our next question is from Joel Sendek from Lazard Capital. Please proceed with your question.

Joel Sendek - Lazard Capital - Analyst

Hi, thanks. Three questions, the first one is do you expect the deal to close before the PDUFA date on October 14th?

Vincent Milano - ViroPharma - President, CEO

The schedule for closing is obviously — we have to get the shareholder vote from Lev and there's some other standard conditions to closing. It — and there's also some deal protection components in here for events that could happen between now and closing. So, it's difficult to say today whether it would close before or after the PDUFA date.

Joel Sendek - Lazard Capital - Analyst

Okay, all right, the second question I have has to do with the approvable letter. The reading Lev's press release, it says there was some additional analysis of the efficacy data. I'm wondering what that was, or if you can expand on that.

Vincent Milano - ViroPharma - President, CEO

The — what Lev has said — Josh is here, but I'll speak on his behalf, is they didn't make specific comments on the details, but the commentary related to the prophylaxis indication were related to the CMC issues. And so, one of the reasons we are moving forward aggressively on the prophylaxis indication is because the FDA's view is different on prophylaxis than acute, clearly.

They took to the BPAC meeting, you know the FDA advisory meeting in May, it was a prophylactic-only discussion and again, it was a unanimous 21 to zero vote in favor of approval. And importantly, there's the discussions and interactions between Lev and the FDA have been focused on labeling discussions and Phase 4 commitments, but there hasn't been any interactions to our knowledge, on the acute. The FDA has focused solely on prophylaxis.

Joel Sendek - Lazard Capital - Analyst

Okay, and then, you know, if you look at the size of the market, and as you described it, Vin, as far as the market size, it seems to me that on a dollar basis, the prophylactic market, at least as you present it is much bigger and I'm trying to triangulate here and figure out if I'm in the right ballpark with regard to pricing.

Although I'm sure you won't answer the pricing question, but if you could just tell me if I'm generally correct. If you're assuming at \$250 million to \$300 million peak market in the US and your one slide said about 135,000 treatments, that would get you to around \$2,000 a treatment, or \$150,000 a year for an individual patient. Are those numbers — am I in the right ball park there?

Vincent Milano - ViroPharma - President, CEO

We aren't going to comment on that today, Josh, I think the way we'd look at it from a pricing perspective is we look at other orphan drug that are out in the marketplace, that's more of a barometer from our perspective.

The math — just to be clear on the number of, I think, 117,000 doses available under all Denizol patients, not all Denizol patients will switch to prophylaxis, but I think the slide on the orphan drug — ultra-orphan drug pricing is a better barometer for you to view.

Joel Sendek - Lazard Capital - Analyst

Okay, actually, the mistake I made, I guess, is I was including acute and prophylaxis. So, if it's just prophylaxis, it will be 117, I was just dividing that into the — your \$250 million to \$300 million peak. Was that — were those peak numbers prophylaxis and acute or both?

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Vincent Milano - ViroPharma - President, CEO

Mostly prophylaxis.

Joel Sendek - Lazard Capital - Analyst

Mostly prophylaxis, okay.

Vincent Milano - ViroPharma - President, CEO

Correct. Again the deals — just to highlight — just relate the deal is structured, we're assuming that prophylaxis is approved first and that we don't have acute, but there certainly could be expectation that there is some off label for acute, but it's a modest amount compared to the prophylaxis indication.

Joel Sendek - Lazard Capital - Analyst

Will there be another panel for acute potentially? Or do you think you'll have to have more data submitted first?

Vincent Milano - ViroPharma - President, CEO

It's — we don't know. Bob, do you have a view on —

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

It's up to the FDA and there's been no feedback on the need for that particular panel for acute. FDA is in a new arena now with the recent implementation of the FDA Amendments Act where FDA is required to have an advisory committee unless they can provide information that would not require it.

So, it's a positive vetting requirement how the review divisions are going to approach that is at the fist in class, or is it going to be all products. Which indication — sub indication to something that the FDA is grappling with and we're looking for evidence. But up to this point, the FDA has not said whether or not the acute indication would require it be back.

Joel Sendek - Lazard Capital - Analyst

Thank you very much.

Vincent Milano - ViroPharma - President, CEO

Thank you, Joel.

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Thanks, Joel.

Operator

Our next question is from Mike King from Rodman and Renshaw, please proceed with your question.

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Mike King - Rodman and Renshaw - Analyst

Good morning, guys. Thanks for taking the question and congratulations on the combination. I just had a couple of mechanical questions about the terms — are there any caps or collars, or is the deal as it's been presented?

Vincent Milano - ViroPharma - President, CEO

There is, Mike, a cap and a collar off of yesterday's close, I believe the range is between \$10.03 and \$15.68. So the value proposition is \$87 million of our stock number of shares to trade within that range. Is that clear?

Mike King - Rodman and Renshaw - Analyst

Yes, and when is that period — just writing it down, when does the period start and when does it finish?

Vincent Milano - ViroPharma - President, CEO

It's during the 20 trading day period prior to closing is when we do the measurement.

Mike King - Rodman and Renshaw - Analyst

20 trading days prior to close. Okay. And can you speak to what the material adverse clauses are in the agreement?

Vincent Milano - ViroPharma - President, CEO

I'll make some general comments but start by saying that the specific terms will be disclosed in an 8-K that we'll be filing in the next few days.

Mike King - Rodman and Renshaw - Analyst

Okay.

Vincent Milano - ViroPharma - President, CEO

But specifically, we identified regulatory matters related to significant delays due to FDA review impairment to regulatory exclusivity and certain specific and significant safety issues. Those are sort of the categories, but we'll disclose in the next few days via an 8-K the entire document.

Mike King - Rodman and Renshaw - Analyst

Okay, and so but — maybe — further to Joel Sendek's question about PDUFA closing and such, I assume, can we get some kind of degree of comfort about — would another approval letter constitute a [mac] or it would have to be worse than that to be —

Vincent Milano - ViroPharma - President, CEO

I think the way we would answer that today is the concept of significant. And so, think about the way that the complete response system works, there's type one and type two.

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Mike King - Rodman and Renshaw - Analyst

Yes.

Vincent Milano - ViroPharma - President, CEO

Type one is not considered a significant issue, and type two is.

Mike King - Rodman and Renshaw - Analyst

Okay. Thanks, that's very helpful.

I wonder if you could talk about sort of the marketing synergies. Do you see any overlap with the current Vancocin sales force in US and can you maybe give us a little foresight into what the approach might be in Europe.

Dan Soland - ViroPharma - VP, COO

So, this is Dan, it's a very good question. We're fortunate to have the Lev team, who we're hoping most will come with us, and they've put together an extremely strong commercialization plan for their product. With regards to sales force. Remember that our Vancosin sales force is really calling on sort of tertiary hospitals that have transplant centers and it's likely that the universe for our targets for the Cinryze products will be primarily allergists. So there's not a whole lot of overlap there.

So, what we believe is the right answer is to have a separate sales force who will specifically target these allergists and we think its sort of on the order of about 20 sales people who will target these key seven or 800 allergists who today have at least one patient that they're caring for with HAE.

Mike King - Rodman and Renshaw - Analyst

In Europe?

Dan Soland - ViroPharma - VP, COO

And I don't think we're ready to comment on Europe at this point in time.

Mike King - Rodman and Renshaw - Analyst

Okay. All right. I'll jump back, in queue.

Vincent Milano - ViroPharma - President, CEO

Thanks, Mike.

Operator

Our next question is from Rachel McMinn from Cowan. Please proceed with your question.

Rachel McMinn - Cowan - Analyst

Thanks, sorry much, I wanted to go back to some of the pricing comments that you've listed here. at least my understanding, some of these companies have thoroughly elaborated an extensive patient assistant/reimbursement infrastructures and I'm wondering in addition to the 20 people that you're hiring on the sales side, whether you think the existing Lev infrastructure is going to be sufficient to support the sophisticated reimbursement on these very expensive orphan products.

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Dan Soland - ViroPharma - VP, COO

So, Rachel, this is Dan and you bring up a very good point and this is really a critical element of being able to successfully commercialize these ultra-orphan drugs. We have to have a very systematic, very careful way of managing these patients so that they're able to get the product that reimbursement is there and that the healthcare professionals are also paid. And the plan that Lev has put together, which is referred to as Lev Care, work with both Lev employees and also with consultants we believe is a very strong system of managing patients for successful therapy.

Rachel McMinn - Cowan - Analyst

So, is it based off of the Genzyme model then? Or do people — like do people within Lev have that type of expertise.

Dan Soland - ViroPharma - VP, COO

I think you can consider it similar to other ultra-orphan drug companies.

Rachel McMinn - Cowan - Analyst

Okay —

Vincent Milano - ViroPharma - President, CEO

So Rachel, though, your question is that are the folks at Lev sufficient enough. The answer is no, we need to augment the team which is what Lev was already thinking about doing anyway, but we'll be —

Dan Soland - ViroPharma - VP, COO

And has a plan for us.

Vincent Milano - ViroPharma - President, CEO

And has a plan to do.

Rachel McMinn - Cowan - Analyst

So I mean I — it just seems like that's going to be perhaps equally as expensive or maybe more expensive than just adding the sales reps. Would you agree with that, that there's a fair amount of money that needs to be invested to [Ceota] to have a successful launch?

Dan Soland - ViroPharma - VP, COO

Well, maybe not as expensive as a sales force, but obviously we believe it to be as important as the sales force. So it's a critical, critical area for us to be successful at for a successful launch.

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Rachel McMinn - Cowan - Analyst

Okay. And then, in terms of the, I guess the timing here of when you're adding the sales people. Will you go ahead and start making changes today or you're going to wait for the deal to actually — I guess you'll just wait for the deal to close and so this product won't really be launching in October, it's probably a 2009 launch.

Dan Soland - ViroPharma - VP, COO

We'll take action immediately to try to put a sales force into the field prior to the launch of the product.

Vincent Milano - ViroPharma - President, CEO

I think the other point, just to be clear, is that we, ViroPharma, are limited with what we can do together with Lev and still post HSR clearance. So we're supportive of Lev's actions to do these activities and conduct these activities, but we have to be careful with what we do together until post date to start clearance.

Rachel McMinn - Cowan - Analyst

Okay, but so you're saying that tomorrow you're going to start going out and looking for sales people and hiring them prelaunch, even before the deal gets closed.

Dan Soland - ViroPharma - VP, COO

Yes, but we again, with the consideration of the HRS.

Rachel McMinn - Cowan - Analyst

Okay.

Vincent Milano - ViroPharma - President, CEO

And I think that just to be clear Rachel, we may or may not be able to do that because the time frame is relatively short right. So our plan would be, if we could find the right people we think could make this product a success with us, based on the facts and circumstances of those times, we would consider bringing those employees onboard to ViroPharma.

Rachel McMinn - Cowan - Analyst

And then, assuming that the deal goes off as planned and you have the kind of launch that you're anticipating, when should we expect the deal to be accretive?

Vincent Milano - ViroPharma - President, CEO

We'll answer that at a later date. We're not prepared to answer that today.

Rachel McMinn - Cowan - Analyst

Will you have updated guidance for us on your call? On your earnings call?

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Vincent Milano - ViroPharma - President, CEO

Not as it relates to the question of future accretion. Remember, our guidance is focused on 2008? So, to the extent that we see changes in our 2008 guidance as a result of this, we will provide it.

Rachel McMinn - Cowan - Analyst

Okay, so we should expect to get updated expense guidance on your call?

Vincent Milano - ViroPharma - President, CEO

You — we always update guidance on all of our quarterly calls, so the answer is yes.

Rachel McMinn - Cowan - Analyst

Okay, okay. Thanks very much.

Vincent Milano - ViroPharma - President, CEO

Thank you, Rachel.

Dan Soland - ViroPharma - VP, COO

Thanks, Rachel

Operator

Our next question is from Meg Malloy from Goldman Sachs. Please proceed with your question.

Meg Malloy - Goldman Sachs - Analyst

Thanks, very much. Couple of them actually. first is, in terms of the expected label, could you clarify the nature of the patients that you studied, that is, were they mostly severe patients. And if so, would you expect a moderate label?

And secondly, could you go through — what is the actual infusion experience. How long does it take? Is every two weeks the right dosing? And would you expect a different treatment regimen for patients at a different severity. If so, is that something that you would study?

And then, separately, could you clarify the patent position and give us an update on manufacturing and then, just finally, what is the pricing like, albeit for acute use in the EU. Thanks.

Vincent Milano - ViroPharma - President, CEO

So, Meg, you asked us a handful of questions there so we'll do our best to remember all of them. I think the first one was to speak to the trial —

Meg Malloy - Goldman Sachs - Analyst

Right.

Vincent Milano - ViroPharma - President, CEO

— design. And then the second one was thoughts around how that impacts the label.

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Meg Malloy - Goldman Sachs - Analyst

Right.

Vincent Milano - ViroPharma - President, CEO

When do we expect a difference in the label versus the trial? And then, you asked about the infusion experience. So, let us start there and then we'll get to manufacturing patents and European pricing.

Meg Malloy - Goldman Sachs - Analyst

Thanks a lot.

Vincent Milano - ViroPharma - President, CEO

So, Josh, maybe you can — at a high level, talk about the trial design.

Josh Schein - Lev Pharmaceuticals - CEO

Sure, we conducted a two part Phase 3 clinical trial. The first part was the acute study and the second part was the prophylactic study. So to participate in the acute study, the patients needed to have a documented history of HAE. To participate in the prophylactic study, patients needed to have participated in the acute study and also needed to have a frequency of attacks of twice monthly.

Now, that was a statistical criterion in order to hit our end point in the study. But it was an enrollment criteria for the study. We're not expecting the label to be limited by the frequency of attacks but we're having those discussions now with FDA.

Patients were treated twice weekly in the clinical trial, so the prophylaxis study had a cross over design in which patients were treated twice weekly with either drug or placebo and then switches and received the other and we simply compared the number of attacks that patient had when they were on drug, compared that to the number of attacks they had when they were on placebo and you saw the results of that study earlier in the presentation.

One of the bonuses of the BPAC meeting on the second of May was on the precise point you had raised, whether or not some patients might do better by increasing the dosage. And so we're also having those discussions with the FDA now in the context of the design of a Phase 4 post marketing study.

So we expect that will be something we look at as a Phase 4 study. The dosing is 10 CCs, it's given by IV injection and the recommended course of administration is one CC per minute. So it's a 10 minute IV injection.

Vincent Milano - ViroPharma - President, CEO

So Bob, would you like to add anything from a standpoint on the labeling.

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

For the labeling and I think that typically the FDA will look at the particular study and the claim can be broad or limited. In other words, by broad saying that for the claim for the prophylaxis of patients with HAE and in some cases, the agency could be — come back and actually state what is in the trail saying that a requirement for at least two attacks per month, but that is not a given. So I've given you the parameters of what the FDA may do.

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Meg Malloy - Goldman Sachs - Analyst

Thanks and if I may just ask here, how long has the bulk of — has the bulk of patients been treated? So do they continue on treatment every two weeks indefinitely, or how does it change every time?

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Yes, we do have ongoing open label studies so all of the patients who participated in the placebo control studies rolled over into open label studies and they do continue primarily on a twice per week regimen.

Meg Malloy - Goldman Sachs - Analyst

Okay.

Vincent Milano - ViroPharma - President, CEO

So, Meg, I forget your manufacturing question.

Meg Malloy - Goldman Sachs - Analyst

I just — so I just to clarify, so you'll be doing Phase 4 studies to assess different dosing regimens in patients with different severity? Is that fair?

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Yes, but keep in mind, as we discussed at BPAC, the — the majority of the patients certainly seem to do well on the twice weekly schedule and we do expect there will be some patients who may benefit from increasing that does and yes, that is the focus of our current discussions with FDA on this side of a four — Phase 4 trial.

Meg Malloy - Goldman Sachs - Analyst

Okay and in terms of the two times per month attack, is that sort of the norm? Or what is the range of experience in HAE patients?

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

I say it's really all over the map, you have patients who have attacks as infrequently as once a year and patients who have attacks as frequently as two or three times per week. But it's important to note that yes, every patient is different and that the frequency of attacks is not the only measure of severity. So if patients have a history of laryngeal attacks for example, those patients may very well be considered good candidates for prophylactic treatment, even if those attacks are infrequent.

Meg Malloy - Goldman Sachs - Analyst

Okay, and if I can just ask one other before we get to manufacturing. Is this a formulation — or a project candidate that might be amendable to a different kind of administration, given the longer half life? Is this something that could be amenable to [subcu], something that could be given in the home?

Dan Soland - ViroPharma - VP, COO

Meg, we think there are opportunities for that.

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Meg Malloy - Goldman Sachs - Analyst

Okay, thank you.

Vincent Milano - ViroPharma - President, CEO

So, Meg the manufacturing question, would you mind restating that?

Meg Malloy - Goldman Sachs - Analyst

Yes, could you tell us where you are on manufacturing and how you'd be prepared for potential launch and also one I didn't want to forget is patent and pricing in Europe.

Dan Soland - ViroPharma - VP, COO

Okay, so as we speak, we're preparing lots of the product to be available, they're being stockpiled. And we believe that at the time of licensure we'll be able to launch the product within a relatively short period of time and that we have capacity that will allow for us to fully aggressively market the product over these next few years.

Meg Malloy - Goldman Sachs - Analyst

Okay.

Vincent Milano - ViroPharma - President, CEO

And on the intellectual property or exclusivity front, there are no patents on this product but there is the orphan drug exclusivity designation by FDA, both for acute and prophylaxis.

Dan Soland - ViroPharma - VP, COO

And a considerable amount of know how by the manufacturer.

Meg Malloy - Goldman Sachs - Analyst

Okay.

Vincent Milano - ViroPharma - President, CEO

And on the pricing and European side, Dan?

Dan Soland - ViroPharma - VP, COO

The pricing on the European side, I think it runs in the sort of \$1,500 to \$2,500 range.

Unidentified Company Representative

Per dose.

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Dan Soland - ViroPharma - VP, COO

Per dose. But remember, also that many of the two products that are on the market in Europe are not available in all countries and they've been licensed on a country by country basis.

Meg Malloy - Goldman Sachs - Analyst

Okay, thanks so much. Very helpful.

Vincent Milano - ViroPharma - President, CEO

Thank you, Meg.

Operator

Our next question is from Brian Rye from Janney Montgomery. Please proceed with your question.

Brian Rye - Janney Montgomery - Analyst

Well, good morning and thanks for taking my question. Most of my —

Unidentified Company Representative

Hi, Brian.

Brian Rye - Janney Montgomery - Analyst

Good morning. Most of my questions have been answered, I guess there's just two, and was wondering if you could update us on, I guess Lev's balance sheet, it looked like at the end of March they had nearly \$14 million in debt, and about \$13 million in cash, but it also looked like they burned around \$9 million or so during the first quarter. I know they haven't yet reported second quarter results. but just wondering if you could provide an update on the debt you'll be assuming and if anything's changed since then.

And then, secondly, sort of re-asking an earlier question, I know you don't know when this will close relative to the October 14th PDUFA date, but I guess I'm interested in your intent and if you'd — and in other words if you're anxious to try and get this shareholder vote scheduled before the October 14th date or what the plan is in terms of that. Obviously there may be some people who would vote differently either before or after that closes. Thank you.

Vincent Milano - ViroPharma - President, CEO

So, I — on the balance sheet front, I don't believe there's any material difference in their balance sheet. Obviously they're currently in a position where they're burning cash and an important element in our discussion with them is that we provided them with the operating capital to allow them to execute on their plans to get to this approval.

With regards to your question, where — I want to say that we're very, very bullish on the probability of success here for prophylaxis. The reason we're bullish again is the fact that that complete response in January was done in January, we understand what the questions are, we understand what the response from Lev has been. I think importantly, and very importantly, is the BPAC meeting, the FDA advisory panel meeting and also the corresponding view from FDA going into that advisory panel meeting were both very, very favorable, unanimous vote.

I think that we're also bullish because the issues from that complete response letter in January, as it related to prophylaxis were, let's call it predominantly CMC related issues and we've had the opportunity to not only see the response from Lev but also visit Sanguin's plant and facilities and do our diligence and we believe that this is a very, very strong partner for this product and a very important element of our confidence in the opportunity here.

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And I'd say, finally, with regards to that is that the discussions that the company is having around labeling and Phase 4 commitments are very strong signals of the agency's view on this product and we understand that nothing is for certain, but this is a high probability — very high probability opportunity in our view.

That being said, we have to go through the process of closing and whether it's before or after the PDUFA date we'll see. But I think, again, from ViroPharma shareholder's perspective we're built in a lot of protections that I think are fair because of things transpire in a very negative way, I think that Lev wouldn't expect us to close. If things don't — if things progress on a good path, I think they would expect us to close.

And with regards to your comment about they may have a different vote before or after, we hope that they see the value in the way we structure this deal, including the upside that could be related to our stock as well as the upside related to the contingent values and we've built fuel protections around it, which again, you can see in more detail as it becomes available when we file our 8-K.

Brian Rye - Janney Montgomery - Analyst

That's helpful. Thank you, Vinny. I guess, just one last clarification. When you mentioned the peak sales that could emanate from this maybe \$250 million to \$300 million, you also mentioned March and the 65% to 70%, are those gross or operating margins?

Vincent Milano - ViroPharma - President, CEO

Those are the gross margins that we have currently put into our analysis.

Brian Rye - Janney Montgomery - Analyst

Great, thanks guys, appreciate it.

Vincent Milano - ViroPharma - President, CEO

Thank you.

Operator

Our next question is from Jason Kolbert from SIG. Please proceed with your question.

Jason Kolbert - SIG - Analyst

We have a bunch of questions. I mean, this is a very competitive space with [varonet] files and potentially a PDUFA date prior to Cinryze. Is one of your protection clauses built in directly addressing that issue?

Vincent Milano - ViroPharma - President, CEO

We have — as I think we alluded to, Jason, and good morning by the way. Impairment to regulatory exclusivity is in — is a category of deal protection. So, the answer is yes.

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Jason Kolbert - SIG - Analyst

Okay. And so one question I have for you, when you look at the market split. I mean it's very clear with Shire acquiring Jerini, Dyax making a — announcing a deal this morning in Europe. I mean there's going to be a lot of competition. What gives you so much confidence that patients are going to want to be driven into a prophylactic therapy? Is there a number of attacks that will be required to justify prophylactic therapy acute.

Dan Soland - ViroPharma - VP, COO

I think it's a very good question and there are even draft guidelines to try to help physicians to decide whether or not to put a patient on prophylaxis and I think, Josh pointed out earlier, its not only the number of attacks, you could argue that one or two attacks a month is enough to put some — to suggest somebody be on prophylaxis. Josh also mentioned earlier that the part of the body that is affected if they have a regular laryngeal attack, I think that's also another reason to put a patient on prophylaxis and there are many quality of life issues.

Remember, these patients oftentimes have difficulty with maintaining a job, may have difficult in being regularly able to go to school. These are situations that — so its going to be a combination of those three areas that is going to decide whether or not its appropriate to have a patient on prophylaxis or not. Is that helpful?

Jason Kolbert - SIG - Analyst

Yes, no. That's — its — that's helpful, but I'm trying to understand also how you get to the patient numbers, because I mean, what we see right now is a relatively small number of HAE patients identified today and so it's a very big gamble that the market is going to expand to even as high as 4,500. I mean, so what gives you so much confidence that you'll get the kind of market expansion that you're betting on here?

Dan Soland - ViroPharma - VP, COO

So, one of the areas was the market research that was done and it's the significant desire by patients and by their physicians to have control, to put — to have a more normal life. And these were significant findings, but here's another parameter, and that is, when you look at the number of patients who on prophylactic anabolic steroids and when you think about this there — and we were asking patients physicians about this, you've got 1,500 patients who were on prophylactic anabolic steroids. There's issues here with gender most of those patients, or a large percentage of those patients are male. So you have a gender issue.

You have an age issue because it's very dangerous to use anabolic steroids in children and believe it or not, there's a geographical preference as to who would be even willing to try anabolic steroids. So, we think that the sort of market opportunity for this product is beyond that 1500 patients. So, I think we're looking at this very optimistically.

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Yes, this is Bob Pietrusko, I have a couple of other comments, one is from the advisory committee that the experts in treating disease had mentioned that when a patient experiences an attack, there is no way for that individual to know whether its going to be a relatively mild swelling in a joint or an extremity, or it will be a full blown laryngeal edema that will require hospitalization and intubations or it could result in death. so the patients are always under this gun so to speak, of not knowing when they start to have an attack what's going to happen.

By using a prophylactic therapy that is very well tolerated, the patients will have an opportunity of twice a week injections of preventing that actual attack from occurring, to have a relatively normal life. So this product will expand the number of patients because of the opportunities that this product will bring and this will be the only product, in the near term, that will have a prophylactic claim because of its half life and supportive data.

Brian Scorning - SIG - Analyst

Hey guys, this is [Brian Scorning]. Good morning, I just had a couple questions too, one CSL Bearing is looking at essentially getting an approval in the [EQ] setting in the same mark. You've already stated that Cinryze is likely to have some off label use in EQ I would assume it would go the same way for CSL Bearing in [plactic], so my question is when you talk about an orphan drug indication where buying power is really significant, what's the prevent the margins from being eroding when essentially two companies are selling the same product?

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Dan Soland - ViroPharma - VP, COO

So, I think there are a number of different reasons here. the first of which is that the Lev product will have a prophylactic indication and the product from CSL does not have any data on prophylaxis, their data is only on acute, so you've got an indication which think is important. I think it's also likely that Cinryze will be on the market prior to the CSL product. So you're going to be the first product on the market.

I think we also, with Cinryze, have a chance of establishing the price and we look to establish the price in a manner that will also control the amount of price sensitivity and we think there are other benefits of the Lev Cinryze product that will allow us to differentiate the product versus the CSL product.

Brian Scorning - SIG - Analyst

And also, guys, you stated that the FDA will be looking at the orphan indications as far as orphan drug exclusivity in two directions and prophylactic in EQ — now is there any documentation from the FDA that said that or have you talked to FDA officials directly and have they responded that they will indeed look at it as two separate orphan drug indications?

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Based on our communication with the — with the FDA. We believe they are looking separately at both indications. Both acute and prophylaxis.

Brian Scorning - SIG - Analyst

Well, I guess my question is more directed to the ViroPharma guys, what sort of diligence have you guys done to ensure that this is indeed the case.

Vincent Milano - ViroPharma - President, CEO

Bob?

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Yes, we've done it independently as well as look at the documentation that Lev has received from the orphan drug division on clarification on this particular topic.

Brian Scorning - SIG - Analyst

Okay. Thank you.

Jason Kolbert - SIG - Analyst

Can I ask — just ask one last question?

Vincent Milano - ViroPharma - President, CEO

Sure.

Unidentified Company Representative

Sure.

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Jason Kolbert - SIG - Analyst

So, one last question has to do back to IP and clearly there's a need for these types of drugs and other indications, drug induced edema, contract activation syndrome, we — I've heard discussions about heart attack. What's the ViroPharma position on looking at ways to develop Cinryze, a C1 INH for maybe other indications beyond HAE, given the fact that you only have orphan protection in HAE.

Dan Soland - ViroPharma - VP, COO

Great question and just to be clear, the reason our desire for the purchase of this drug is primarily for HAE and for the prophylaxis market opportunity and we think that that is going to be our initial and our primary focus for the drug product. But your point is valid. There are a number of different disease indications where the drug may offer benefit. But again, our initial focus and our primary focus is going to be on prophylactic treatment for HAE patients.

Jason Kolbert - SIG - Analyst

Thank you very much from Brian and I, we appreciate it.

Vincent Milano - ViroPharma - President, CEO

Thank you.

Unidentified Company Representative

Thanks, guys.

Operator

Our next question is from [Yale Gen] from Maximum Group. Please proceed your question.

Yale Gen - Maximum Group - Analyst

Good morning, all. Thanks for taking the questions.

Dan Soland - ViroPharma - VP, COO

Hi, Yale.

Yale Gen - Maximum Group - Analyst

Hi. I think most of the questions been answered so I got about two in here. the first one is the Lev has recently signed an agreement with CVS Caremark and FFF for the commercialization efforts and what does that stands and what is ViroPharma going to do with that?

Dan Soland - ViroPharma - VP, COO

So, I don't think we want to be real specific here, but just to be fair, I think Lev has put together a plan for I think is going to be a very successful distribution of the product. And using a contract warehouse like FFF is very similar to how we distribute Vancocin today and specialty pharmacies and the services that specialty pharmacies provide are going to be critical to the success of this product. So I cant — I guess we cannot say for certain, but it's likely that we're going to follow very carefully the Lev plan for distribution of this product.

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Yale Gen - Maximum Group - Analyst

So, it will mostly likely may continue to use that venue for moving things forward?

Dan Soland - ViroPharma - VP, COO

Most likely.

Unidentified Company Representative

Yes.

Yale Gen - Maximum Group - Analyst

Okay, great. The second question is to sort of continue on the previous people have asked about the 1,500 patients if you consider that as a low hanging fruit, how was — what is the plan, at this moment of thinking of expanding into a sort of broader market, a broader patient population?

Dan Soland - ViroPharma - VP, COO

You bring up a good point and its interesting, of these 1500 patients who are on anabolic steroids, I think the vast — the largest portion of them are adult males. So it immediately conjures up an opportunity for females, for a large portion of females to be prophylaxes with Cinryze, and also, an opportunity for children. So, we think that the real opportunity is beyond this 1500 patients today who are on prophylactic anabolic steroids.

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

I would only add to that that for the — regarding the demographic of your typical prophylactic patient in our Phase 3 prophylactic study, 20 of the 22 patients were females. There were only two men enrolled in that study. So it was a very clear unmet clinical need in the female population. And —

Yale Gen - Maximum Group - Analyst

Okay, thanks, Bob. Specifically, would that consider — I mean the initial one, would that be patient has a laryngeal attack before or those are the primary, sort of first tier of target that you could try to reach?

Dan Soland - ViroPharma - VP, COO

No, I think they're really — again, there are really three areas of focus. One is the number of attacks on a monthly or weekly basis, I mean that's clearly a big driver. I think the second is what you bring up is patients who have had a laryngeal attack, which is a very scary life threatening situation. They're also likely to want to be on prophylaxis. And I think, thirdly is this quality of life issue.

It's difficult for these patients to maintain — to have a job because they're out on sick leave on a regular basis, its difficult for them to be able to participate in education. There's a whole host of reasons why patients, we believe, and the market research suggests, would want to be on a regular prophylactic C1 inhibitor therapy.

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Yale Gen - Maximum Group - Analyst

Okay, great. And just a little bit explanation to that is that the — for the people currently taking the steroid which is much lower cost and you jump into a much — potentially a much higher cost product. What's the status currently you're expecting with some Medicare and Medicaid or other reimbursement agency in terms of — payers in terms of the status for the discussion?

Dan Soland - ViroPharma - VP, COO

So, fortunately, the commercial team at Lev is extensive work on figuring out the different payers that cover these patients and there has been a lot of contact with these payers and we've done a review of these contacts and there does not appear to be a significant disconnect with these payers in their willingness to pay for therapy for these patients. And so we're assured of that. Plus, there's a very aggressive patient assistance program to help to make sure that no patients left behind so that all patients who have this terrible disease will be able to benefit from Cinryze.

Yale Gen - Maximum Group - Analyst

Okay, great. Thanks a lot for answering those questions.

Dan Soland - ViroPharma - VP, COO

Thank you, Yale.

Vincent Milano - ViroPharma - President, CEO

Thanks, Yale.

Operator

Our next question is from Biren Amin from Stanford Group. Please proceed with your question.

Biren Amin - Stanford Group - Analyst

Yes, hi. Thanks for taking my questions. In your slide, I think you estimated that the US population is 4,600 patients, but in the July '08 Lev presentation, I believe they had estimated 4,000 patients in the US. Could you maybe describe the discrepancy —

Dan Soland - ViroPharma - VP, COO

Sure.

Biren Amin - Stanford Group - Analyst

Were there maybe 600 patients that were diagnosed in the last two weeks, possibly?

Dan Soland - ViroPharma - VP, COO

Sure, so the 4,600 comes directly from the HAE patient association and that was a number that was made public at the May 2nd advisory committee with the FDA. So, that's where that 4,600 number comes from.

Vincent Milano - ViroPharma - President, CEO

And the 4,000 I believe, was from market research.

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Dan Soland - ViroPharma - VP, COO

Yes, and also, an earlier number from the patient association.

Biren Amin - Stanford Group - Analyst

Okay, and with regards to the patients in the open label. Could you maybe tell us how many of those patients have opted for open label are continuing with Cinryze therapy today?

Dan Soland - ViroPharma - VP, COO

I think all of them.

Bob Pietrusko - ViroPharma - VP, Global Regulatory Affairs and Quality

Virtually all the patients who participated in the placebo controlled studies continued on Cinryze therapy.

Biren Amin - Stanford Group - Analyst

Okay. And I guess, a question for Vinny, I guess with the structure of the deal, acquisition versus in licensing. Why choose an acquisition versus an in licensing model and also, how did the Shire deal for Jerini influence the shape and size of the deal?

Vincent Milano - ViroPharma - President, CEO

So the — with regards to the first question, the opportunity itself has been worked on for over nine months and Lev — Lev has very good people, but they're a small organization and the benefits of a licensing deal, frankly are probably not very good for either company. So it was a much — a much cleaner situation for us to acquire the company outright, bringing on the Lev employees who will help in the successful execution of the Cinryze business.

With regards to the second question on the Jerini deal. We know this is a competitive space and in the context of what we've been doing for months with Lev, frankly, it didn't impact the way we thought of this deal. We imagined that Shire was interested in buying Jerini because of the approval in the European market. although they have a non-approvable situation here in the US market for their product. So, it didn't shape the contour of the deal in any real way.

Biren Amin - Stanford Group - Analyst

Great, thanks.

Vincent Milano - ViroPharma - President, CEO

Thank you.

Operator

We have a question from Stephen Willey from Thomas Weisel. Please proceed with your question.

Stephen Willey - Thomas Weisel - Analyst

Hey, good morning, guys.

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Vincent Milano - ViroPharma - President, CEO

Hey, Steve.

Unidentified Company Representative

Hey, Steve.

Stephen Willey - Thomas Weisel - Analyst

Maybe this question is best suited for Colin, but is there a biological benefit between actual replacement therapy versus hitting the pathway? So for instance between the Lev drug and say the Dyax and the Jerini drugs. And does that benefit kind of pop up in the clinical data?

Vincent Milano - ViroPharma - President, CEO

Colin?

Colin Broom - ViroPharma - VP, Chief Scientific Officer

Well, you're right. There is always an advantage to stopping at cascade at the beginning rather than later downstream. But I think the most compelling difference biologically is the long elimination half life. You are — have a half life in a few days as opposed to a half life in a few hours with these other agents, the Dyax and the Jerini compound.

Stephen Willey - Thomas Weisel - Analyst

Do you think the half life then might be a pretty significant obstacle with respect to the Dyax drug gaining any off label use in the prophylactic setting?

Colin Broom - ViroPharma - VP, Chief Scientific Officer

Well, absolutely. The long elimination half life in a few days, with Cinryze, is really one of the major advantages of this product.

Stephen Willey - Thomas Weisel - Analyst

Okay, yes because I just think about the prophylactic setting and obviously delivery becomes pretty important there and you have a subcu version of a Dyax drug which you can administer at home and eliminate the need to travel to an infusion center once or twice a week. So, if the half life is a big obstacles there, I think that's a pretty significant component then.

Colin Broom - ViroPharma - VP, Chief Scientific Officer

Yes, I mean there will be some individuals who like to take the risk of treating when symptoms have already started. But like a number of clinical situations, things can quickly get out of hand and it's going to be too late.

I've also given the relatively short half life, other things to look at will the duration and effect. I mean — will you need to give multiple subsequent injections, and also, I would to exclude in the ore sever cases that have gone maybe partially responding, you may want to use more than one — one therapy, as often happens. You have a patient that you're faced with whose developed laryngeal edema, you may well use a number of different modalities.

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Dan Soland - ViroPharma - VP, COO

Just a follow on. You also brought up convenience and remember, and Josh, correct me if I'm wrong, but in the ongoing open label trial, there are a group of patients who go to the clinic for the infusion. There are a group of patients who have a home health nurse come to their home. And there's a group of patients who self administer. So, we think that Cinryze provides a very convenient way to control HAE disease for these patients.

Stephen Willey - Thomas Weisel - Analyst

Okay.

Josh Schein - Lev Pharmaceuticals - CEO

Yes, there are currently 26 patients that are importing Ceter, the existing Dutch product for self administration. And we believe, based on our market research, that most patients will certainly opt for care in the home, either by self-administration or administration by a health care professional. Though some may opt to go to a treatment center.

Stephen Willey - Thomas Weisel - Analyst

Great, thanks a lot.

Dan Soland - ViroPharma - VP, COO

Thank you.

Operator

Our next question is from Thomas Wei from Piper Jaffray. Please proceed with your question.

Thomas Wei - Piper Jaffray - Analyst

Oh thanks. Just a quick follow up on the patient population. Do you have a sense of how many patients are actually hospitalized on an annual basis for this?

Dan Soland - ViroPharma - VP, COO

There's like — we know that there is like 20,000 to 30,000 emergency room visits by these patients. So, it's not insignificant at all.

Thomas Wei - Piper Jaffray - Analyst

And then you had intimated there might be differences between Cinryze and Berinet but what would those be besides the actual indications that each company is seeking?

Dan Soland - ViroPharma - VP, COO

I don't think we want to speak about those at this point in time, Thomas.

Thomas Wei - Piper Jaffray - Analyst

Okay, thank you.

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Operator

Your next question is from Mike King from Rodman and Renshaw.

Mike King - Rodman and Renshaw - Analyst

Hi, sorry to prolong the call guys, I just wanted to know the patent for Cinryze runs out in 2017, correct me if I'm wrong.

Vincent Milano - ViroPharma - President, CEO

There's no patent for Cinryze, Mike. Its the orphan exclusivity is the exclusivity proposition.

Mike King - Rodman and Renshaw - Analyst

Okay, and then you say — but then the disclosures the Lev disclosure that could be extended for five years, how would you propose that could be done?

Vincent Milano - ViroPharma - President, CEO

Not familiar with that point, Mike. Let us look at it.

Mike King - Rodman and Renshaw - Analyst

All right. I'll take it offline.

Vincent Milano - ViroPharma - President, CEO

Thank you very much, everyone, for your time and attention this morning. Again, we're very excited about this opportunity and we will again remain as communicative as possible and we look forward to speaking with you again soon. Thank you very much and have a great day.

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