United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

October 11, 2019
Date of Report (Date of earliest event reported)

Health Sciences Acquisitions Corporation
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38906**	**83-2771572**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

412 West 15th Street, Floor 9 New York, NY	**10011**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(646) 343-9280**

N/A
(Former name or former address, if changed since last report)

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

☐ Written communications pursuant to Rule 425 under the Securities Act

☒ Soliciting material pursuant to Rule 14a-12 under the Exchange Act

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

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Units, each consisting of one share of Common Stock, $0.0001 par value, and one Warrant entitling the holder to receive one half share of Common Stock	HSACU	The Nasdaq Stock Market LLC
Shares of Common Stock, $0.0001 par value, included as part of the Units	HSAC	The Nasdaq Stock Market LLC
Warrants included as part of the Units	HSACW	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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. ☐

IMPORTANT NOTICES

Participants in the Solicitation

Immunovant Sciences Ltd. ("Immunovant"), Health Sciences Acquisitions Corporation ("HSAC"), and their respective directors, executive officers and employees and other persons may be deemed to be participants in the solicitation of proxies from the holders of shares of HSAC common stock in respect of the Business Combination described herein. Information about HSAC's directors and executive officers and their ownership of HSAC common stock is set forth in HSAC's preliminary proxy statement dated October 2, 2019 (the "Preliminary Proxy Statement") filed with the Securities and Exchange Commission (the "SEC"), as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of such filing. Other information regarding the interests of the participants in the proxy solicitation are included in the Preliminary Proxy Statement pertaining to the Business Combination. These documents can be obtained free of charge from the sources indicated below.

Additional Information and Where To Find It

In connection with the transaction described herein, HSAC has filed and will file relevant materials with the SEC, including the Preliminary Proxy Statement and a definitive proxy statement on Schedule 14A. Promptly after filing its definitive proxy statement with the SEC, HSAC will mail the definitive proxy statement and a proxy card to each stockholder entitled to vote at the special meeting relating to the transaction. INVESTORS AND SECURITY HOLDERS OF HSAC ARE URGED TO READ THESE MATERIALS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND ANY OTHER RELEVANT DOCUMENTS IN CONNECTION WITH THE TRANSACTION THAT HSAC WILL FILE WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT HSAC, IMMUNOVANT AND THE TRANSACTION. The definitive proxy statement, the preliminary proxy statement and other relevant materials in connection with the transaction (when they become available), and any other documents filed by HSAC with the SEC, may be obtained free of charge at the SEC's website (www.sec.gov) or by writing to Health Sciences Acquisitions Corporation, 412 West 15th Street, Floor 9, New York, NY 10011.

Forward-Looking Statements

This Current Report on Form 8-K and the documents incorporated by reference herein (this "Current Report") contain certain "forward-looking statements" within the meaning of "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "shall," "may," "anticipate," "estimate," "would," "positioned," "future," "forecast," "intend," "plan," "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Examples of forward-looking statements include, among others, statements made in this Current Report regarding the Business Combination (as defined below) contemplated by the share exchange agreement (the "Share Exchange Agreement") among HSAC, Immunovant, Roivant Sciences Ltd., and the stockholders of HSAC (the "Business Combination"), including the anticipated initial enterprise value and post-closing equity value, the benefits of the Business Combination, integration plans, expected synergies and revenue opportunities, anticipated future financial and operating performance and results, including estimates for growth, the expected management and governance of the combined company, and the expected timing of the Business Combination. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on HSAC and Immunovant managements' current beliefs, expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (1) the occurrence of any event that could give rise to the termination of the Share Exchange Agreement; (2) the outcome of any legal proceedings that may be instituted against HSAC, the combined company, or others following the announcement of the Business Combination and the Share Exchange Agreement; (3) the inability to complete the Business Combination due to the failure to obtain approval of HSAC's stockholders or to satisfy other conditions to closing in the Share Exchange Agreement; (4) changes to the proposed structure of the Business Combination that may be required or appropriate as a result of applicable laws; (5) the ability to meet the Nasdaq Stock Market LLC ("Nasdaq") listing standards following the consummation of the Business Combination; (6) the risk that the Business Combination disrupts current plans and operations of Immunovant as a result of the announcement and consummation of the Business Combination; (7) the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, the ability of the combined company to grow and manage growth profitably, maintain relationships with third parties and partners, obtain adequate supply of raw materials and retain its management and key employees; (8) costs related to the Business Combination; (9) changes in applicable laws or regulations; (10) the possibility that Immunovant or the combined company may be adversely affected by other economic, business, regulatory, and/or competitive factors; (11) Immunovant's estimates of expenses; (12) the impact of foreign currency exchange rates and interest rates fluctuations on the results of Immunovant or the combined company; and (13) other risks and uncertainties indicated in the Preliminary Proxy Statement and the definitive proxy statement to be filed by HSAC with the SEC in connection with the Business Combination, including those under "Risk Factors" therein, and other documents filed or to be filed from time to time with the SEC by HSAC.

A further list and description of risks and uncertainties can be found in HSAC's Preliminary Proxy Statement and the definitive proxy statement on Schedule 14A that will be filed with the SEC other documents that the parties may file or furnish with the SEC, which you are encouraged to read. Any forward-looking statement made by us in this Current Report is based only on information currently available to HSAC and Immunovant and speaks only as of the date on which it is made. HSAC and Immunovant undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise, except as required by law.

Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference is a copy of the script from the joint conference call that took place on Friday, October 11, 2019 at 8:30 am EDT, discussing the Business Combination.

Exhibit 99.1 is being furnished pursuant to Item 7.01 and shall not be deemed to be filed for purposes of Section 18 of the Exchange Act or otherwise be subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1*	Script from Joint Conference Call dated October 11, 2019

* Furnished but not filed.

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.

Dated October 11, 2019

HEALTH SCIENCES ACQUISITIONS CORPORATION

By: /s/ Roderick Wong
Name: Roderick Wong, MD
Title: Chief Executive Officer

Exhibit 99.1


VIAVID
communications simplified.
Immunovant and Health Sciences Acquisitions Corporation
Discuss Plans to Merge
October 11, 2019

Immunovant and Health Sciences Acquisitions Corporation Discuss Plans to Merge, October 11, 2019

C O R P O R A T E P A R T I C I P A N T S

Dr. Roderick Wong, *Chief Executive Officer, Health Sciences Acquisitions Corporation*

Dr. Pete Salzmann, *Chief Executive Officer, Immunovant*

Dr. Naveen Yalamanchi, *Chief Financial Officer, Executive Vice President, Health Sciences Acquisitions Corporation*

C O N F E R E N C E C A L L P A R T I C I P A N T S

Christopher Marai, *Nomura Instinet*

Brian Skorney, *Baird*

Gbola Amusa, *Chardan*

Sam Slutsky, *LifeSci Capital*

P R E S E N T A T I O N

Operator:

Good morning. My name is Melissa, and I will serve as your conference call Operator. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require Operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

Joining me on the call today will be Dr. Roderick Wong, Chief Executive Officer of Health Sciences Acquisitions Corporation, Dr. Naveen Yalamanchi, Chief Financial Officer and Executive Vice President of Health Sciences Acquisitions Corporation, Dr. Pete Salzmann, Chief Executive Officer of Immunovant, and Dr. Sandeep Kulkarni, Chief Operating Officer of Immunovant, and Dr. Robert Zeldin, Chief Medical Officer of Immunovant.

Before we begin, I would like to remind everyone that today's conference call will include certain forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, both as amended. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to various risks and uncertainties, assumptions, including assumptions about general economic, market, industry and operational factors, known or unknown, which could cause the actual results to vary materially from those indicated or anticipated.

Now, without further delay, I would like to turn the call over to Dr. Roderick Wong. Thank you. Dr. Wong, you may begin.

Dr. Roderick Wong:

Thank you, Operator.

When we incorporated HSAC, our goal was to leverage our research coverage of innovative drugs and devices and our pipeline of private investment opportunities to find a scientific program with the potential to be a transformative therapy for patients with high unmet need. We think IMVT-1401 is a promising molecule that has the potential to be a pipeline in a product.

To provide a bit of context, we have been tracking the development of 1401 for several years now as part of our competitive analysis of the FcRn drug class, which we expect will become a cornerstone therapy in auto-antibody driven disease. We have been impressed by its ability to be given subcutaneously, and its robust reduction in IgG levels in a comprehensive Phase 1 program.

Over the last couple of years, we have been equally impressed by the development choices and execution by the Immunovant team. We think Graves' ophthalmopathy, myasthenia gravis, and warm autoimmune hemolytic anemia position the company with three solid potential initial paths to market.

Finally, we are excited to have gained the support of industry leading life-sciences investors, who have collectively agreed to provide over $100 million in connection with this transaction to fund the development of 1401.

Now, I'd like to turn the call over to Naveen to discuss some of the highlights of the transaction.

Dr. Naveen Yalamanchi:

Thank you very much, Rod.

We are ecstatic to have put such a compelling asset and an experienced management team with which to consummate our business combination. Assuming that no shares of HSAC are redeemed, the combined company is expected to have approximately 55.6 million non-redeemable shares outstanding, which implies a market capitalization of approximately $556 million at the negotiated transaction price of $10 per share. We hope that the transaction will close in December 2019, pending standard regulatory reviews. By securing backstop and voting agreements with a number of leading investors, we expect that the Company will have more than $100 million of cash at closing after taking into account cash raised in connection with the transaction.

I'd also like to take a minute to point out some important features that make this transaction distinct from most precedent SPAC deals. Based on our confidence in the quality of IMVT-1401 and in the Immunovant team to execute on its vision, HSAC has agreed to forfeit 100% of its private sponsor warrants. In addition to agreeing to cancel its sponsor warrants, HSAC further agreed to place most of its sponsor shares in escrow, to be delivered only after Immunovant's share price appreciates considerably. We have postponed a portion of the typical sponsor compensation until such time as Immunovant's stock exceeds $31.50, more than triple the transaction price of $10.00.

I think it's important to point out that we believe concessions of this nature are in the best interest of all HSAC investors and make this particular transaction quite different from prior SPACs. We would not have made these concessions without our conviction in the prospects for Immunovant and IMVT-1401.

Our confidence in Immunovant is in no small measure linked to its exceptional management team, led by CEO Pete Salzmann.

On that note, I'll now turn the call over to Pete.

Dr. Pete Salzmann:

Thank you, Naveen.

At Immunovant, our mission is to enable normal lives for patients with autoimmune diseases. During my 20 years at Lilly, where I recently led the firm's U.S. Immunology Business Unit, and before that as a physician, I've personally come to know countless autoimmune patients. Though the category encompasses a variety of conditions and disease manifestations, I can tell you one thing these patients all have in common is that they just want to feel normal again. With this in mind, we believe the future for FcRn-targeted therapies is very bright. The current body of scientific knowledge is only just scratching the surface of what FcRn-targeted therapies may have to offer.

Within the anti-FcRn class, we believe the potency of IMVT-1401 and the ability to administer IMVT-1401 as a simple subcutaneous injection represent important differentiating features. For the patient, whose journey with the disease often lasts a lifetime, there's nothing more important than ease of administration. The ability to take back control over their health by self-administering 1401 with a quick, subcutaneous injection, in the privacy of their own home, offers life-changing potential.

Given that targeting FcRn offers great promise in a number of disease areas, we've developed a two-pronged strategy. Specifically, we strive to be best-in-class in target indications where the anti-FcRn approach has already established clinical proof-of-concept, and first-in-class in target indications with clear biologic rationale and no in-class competition.

To these ends, I am proud of the many milestones delivered by the Immunovant team this year, including completion of a comprehensive Phase 1 program demonstrating robust IgG reductions of 78% with simple weekly subcutaneous injections of 680mg. Note that the Immunovant team ran this trial in Australia and Canada and successfully dosed 99 healthy volunteers across cohorts.

We've also initiated a broad Phase 2 program with both first-in-class and best-in-class potential in multiple diseases with high unmet patient need. Importantly, 1401 was also generally well tolerated in this good-sized Phase 1 trial.

Over the next 20 months, we anticipate four data readouts. In the first quarter of 2020, we expect to report initial results from our Phase 2a study in Graves' ophthalmopathy, a potentially sight-threatening disease affecting an estimated 15,000 to 20,000 patients in the United States each year.

Our Phase 2b study in the same indication is expected to report initial results in early 2021.

Additionally, in the first half of 2020, we expect to report top-line results for our Phase 2a study in myasthenia gravis and initiate a pivotal Phase 3 study shortly thereafter.

Finally, we anticipate reporting initial results from a Phase 2a study in our third indication, warm autoimmune hemolytic anemia by the fourth quarter of 2020. Warm autoimmune hemolytic anemia is a serious blood disorder affecting approximately 42,000 patients in the U.S. and 66,000 patients in Europe. As is true for the other two indications we are pursuing, there is a lot of unmet medical need in this condition.

At Immunovant, we believe that the field of FcRn-targeted therapy is still in its infancy, and that the possibilities for IMVT-1401 expand far beyond our initial target indications of myasthenia gravis, Graves' ophthalmopathy, and warm autoimmune hemolytic anemia.

We believe we are just getting started on our mission to enable normal lives for patients with autoimmune diseases.

With that, I will ask the operator to open the call for Q&A.

Operator:

Thank you. At this time we'll be conducting a question-and-answer session. If you'd like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key.

Our first question comes from the line of Christopher Marai with Nomura Instinet. Please proceed with your question.

Christopher Marai:

Good morning. Thank you for taking the question. I was curious if you could perhaps expand for us upon on how your FcRn approach is different from some of the others. Specifically, looking at some of your Phase 1 protocols, you've tested some higher doses it looks like you're going to be bringing into the Graves' trial coming up. Could you maybe expand on toxicity seen at the higher doses, if any? Then if those higher doses conferred any further reduction in IgG, or are you sort of maxed out at the doses that you were exploring? And then I have a follow-up. Thank you.

Dr. Pete Salzmann:

Hi Chris. It's Pete. Thanks for that question or series of questions. There are some important questions there.

Let me take the first one regarding the differentiation of our program versus other FcRn programs. I think this is a market that's going to be subcutaneous. Patients are going to demand a simple, easy-to-administer therapy. If we look at the various subcutaneous programs, we have demonstrated the most IgG reduction across any subcutaneous program. In fact, as you reference, in our Phase 1 trial, we did test both subcutaneous and intravenous dosing in the single ascending dose trials and showed that the reduction in IgG was the same whether 1401 is delivered subcutaneously or intravenously. That allows us to build our entire development program around subcutaneous dosing.

We did have a single ascending dose arm that was higher than 680mg just delivered once. However, in our multiple ascending dose trial, the 680mg – the reduction that was achieved with 680mg – did plateau and therefore we believe we've achieved the maximum reduction in IgG at that dose. Again, at around 78%. That was the mean across that cohort.

In that sense I think we're very happy with our dose. We are taking the 680mg dose as well as the 340mg dose into all of our Phase 2 trials, so we'll be testing both of those doses.

Christopher Marai:

Okay, great. Just with respect to safety, you know, several FcRn approaches are seeing things like headaches, potentially injection sight reactions but also albumin reduction. Can you comment on what you're seeing with respect to that? Any sort of differentiation, any other AEs that you've seen that might be of concern?

Dr. Pete Salzmann:

Yes. Thanks for that question.

As I mentioned in the opening statement, we conducted a large Phase 1 trial with 99 healthy volunteers. In that trial – you mentioned headaches – so, in our highest dose, multiple ascending dose cohort, the 680mg subcutaneous dose, there are actually no headaches in that cohort. Across all the various cohorts, we didn't see dose dependent headaches nor did we see any significant prevalence of headaches.

In terms of injection site reactions, the definition of injection site reaction requires pain or tenderness. We only had across the entire group of 99 subjects, there were only four – three who received 1401 and one who received placebo – that had any injection site pain, and it was mild pain that resolved after a short period of time. This is as painless injection as we've seen to date.

In terms of albumin reductions, we did see dose dependent, reversible, and asymptomatic albumin reductions in the Phase 1 trial.

Dr. Roderick Wong:

This is Rod. I would just add that there are a kind of "perfect knock out model" in that there are patients born with close to 0% albumin and those people, in the literature, are generally asymptomatic with the exception of maybe a little bit of occasional edema, but they're basically healthy people.

Christopher Marai:

That's helpful. Thank you. Then maybe lastly on the clinical path that you're progressing on. Why Graves' sort of over some of the others, and then with WAIHA it looks like Alexion is going to be progressing in the clinic there pretty quickly. How do you see yourselves competing, whether it's for patient enrollment or on a timeline basis with that program? That's my final question. Thank you.

Dr. Pete Salzmann:

Yes. As we looked at the variety—first of all there's a lot of opportunity in the FcRn space because of the many diseases that are mediated by pathogenic IgG and because of the fact that for pretty much all of these conditions, there's really not a good standard of care. There's a lot of unmet need, and that gives many opportunities to choose different indications.

We selected these indications based on the clinical validity in the case of myasthenia gravis and warm autoimmune hemolytic anemia. There's already some data within the FcRn class or in the case of Graves' ophthalmopathy, strong biologic plausibility based on a couple of factors; the observation that the degree of ophthalmopathy in Graves' ophthalmopathy correlates with the titer of anti-thyroid stimulating hormone receptor antibodies and also some small studies with IVIG that demonstrate a benefit in Graves' ophthalmopathy. This offers us a nice first in class opportunity.

In addition, all three of these indications have a clear regulatory path with very clear endpoints, and that allows us to run a faster and cleaner program. So, those were factors as well.

Christopher Marai:

Thank you.

Dr. Pete Salzmann:

Thanks for the questions.

Operator:

Thank you. Our next question comes from the line of Brian Skorney with Baird. Please proceed with your question.

Brian Skorney:

Good morning, guys. Thanks for taking some questions here. I guess for me, as you kind of thought about your strategic financing alternatives, what lead you down the path of SPAC transaction versus more traditional IPO or other routes of financing, and what do you think is kind of attractive about this sort of transaction?

Dr. Pete Salzmann:

Thanks for that question. What was attractive about the SPAC was less the SPAC mechanics themselves and more this particular SPAC, Health Sciences Acquisitions Corporation. What I mean by that is that RTW under Rod's leadership really assembled a tremendous syndicate of leading life sciences investors. So, as we look at the owners within Health Sciences Acquisitions Corporation, they're really the investors that we would want to have owning Immunovant under any path to the public market. So, that made this particular SPAC very attractive.

In addition to that, the size of the trust fund is right about the amount of money that we were looking to raise and then the availability of the earnouts align some long-term incentives which is another nice feature.

It's probably important also to maybe take that question from the other angle. Rod, I don't know if you want to talk a little bit about how HSAC went out looking for targets and selected Immunovant.

Dr. Roderick Wong:

Sure. Happy to. It was most important to us to find something where our long-term interests would be aligned. FcRn is an area that we've spent a lot of time on over the last several years, and this is an asset that we've been interested in. Even preceding Immunovant's in licensing between two and three years ago. We're thrilled to have the opportunity to back this asset and the team which we think has done a wonderful job executing on their plans over the last two years.

Brian Skorney:

Great. Then maybe following the close of the transaction. What do you sort of estimate your burn will be and what sort of cash runway does the financing provide for you?

Dr. Pete Salzmann:

Right. We're estimating that, again, a close before the end of the year, and that we'll close with more than $100 million on the books that will take us to the second half of 2021.

Brian Skorney:

Thanks, guys.

Operator:

Thank you. Our next question comes from the line of Gbola Amusa with Chardan. Please proceed with your question.

Gbola Amusa:

Thanks for taking my call. I did drop off for about two minutes so I hope this wasn't asked. Can you talk about competitors working on sub-cu and why the profile of 1401 is interesting relative to potential competition-driven sub-cu?

Dr. Pete Salzmann:

Yes, great question. That hasn't been asked yet. I think patients absolutely are going to want a product that's efficacious and has a good safety profile. Beyond that, the ease of administration is, I think, an important differentiating feature that's recognized essentially by everyone competing in the space and everyone is looking to develop a subcutaneous formulation.

In the case of 1401, I like to say 1401 was "born sub-cu." What I mean by that is HanAll, the original developer of 1401, specified subcutaneous administration as a feature that they would select for when developing this antibody. Specifically what that means is, back when they had 40-plus candidate antibodies that they were screening for potency against the FcRn receptor, they also made those antibodies in small aliquots and determined which ones could be made easily in a concentration of 150 mg/ml or greater required for subcutaneous administration and they made them at that concentration in a non-viscous, non-precipitating form. Antibodies that couldn't be easily dissolved were excluded from advancing. Ultimately, 1401 had among the highest potency of all their candidates and was easily soluble.

So that was a really deliberate approach to developing a subcutaneous formulation, which is different than the typical approach which is to develop the antibody for potency against the target, wait until some additional data has validated some other elements of the antibody, such as safety, and then begin to work on converting it to a subcutaneous formulation. The history of antibodies going from IV to sub-cu at that stage in development, I think is fraught with a lot of timeline delays or in some cases antibodies never made it from IV to sub-cu. So we see this as a sustainable competitive advantage and something that patients will really value.

Gbola Amusa:

Since you mentioned HanAll, what are the economics to HanAll? Then a second question is how you're managing competition for patients enrolling in trials?

Dr. Pete Salzmann:

Yes, thanks for those two questions. HanAll, Roivant paid an upfront licensing fee of $30 million to HanAll, and then there are an additional set of milestones of approximately $450 million spread across a whole variety of endpoints both development, regulatory and sales milestones, and in addition there are royalties in the mid single-digits to low double-digits across the sales of 1401 in the future.

Then your second question, Gbola, was?

Gbola Amusa:

Managing competition for patients enrolling in your trial.

Dr. Pete Salzmann:

Yes, thanks. I think the—look, this is an area like all clinical development today where I think there's a couple of important factors in terms of recruiting patients in the clinical trials. The first thing is to have a trial that makes sense to investigators in terms of the inclusion/exclusion criteria and what's being measured, and I think in that case we've hit the mark. I think the investigator's enthusiasm for the potential of the molecule is also really important. As I've been out meeting with principal investigators across our different trials, there's a lot of enthusiasm for a simple subcutaneous injection that delivers high pharmacodynamic effect.

Then the third thing is getting to know those investigators, being available to answer questions from the sites, being responsive, and that's all things we're focused on to ensure that our clinical trial execution is good.

Gbola Amusa:

Got it. Thank you.

Operator:

Thank you. Our next question comes from the line of Sam Slutsky with LifeSci Capital. Please proceed with your question.

Sam Slutsky:

Hey, good morning everyone, and thanks for the questions. For Pete and team, I guess given the broad potential of targeting FcRn, how are you thinking about indications beyond MG, GO and WAIHA? Then, also to that end, how did you choose these three as your first two indications go into.

Dr. Pete Salzmann:

Yes, thanks Sam. Again, the first two were chosen based on the strong clinical validation, in some cases, or the ability to be first in class where there was strong biologic rationale, combined with the fact that for these first three indications there's a really clear regulatory pathway with a well-described primary endpoint. Also, the size of these three indications is among the larger within the pathogenic IgG space.

In terms of which indications to pursue next, and I'm sure we will pursue others, those decisions will be based on a couple of things. Where we see clinical validation from another program, we would definitely jump on that if there's a program that's achieving good results. Again, with their intravenous dosing since all the other programs to date are intravenous, I think we have a strong value proposition to come behind as a fast follower and have a potential for a best-in-class offering with the strong pharmacodynamic activity combined with a subcutaneous injection administration.

Then, in addition to that, I think over time as we have more indications, there will be opportunities for synergies across the indications and we'll consider that as well.

Sam Slutsky:

Got it. Makes sense. Then, you may have mentioned this earlier on the call, but if you could walk us through some of the timelines on the clinical side. Study starting, readouts, etc.?

Dr. Pete Salzmann:

Right. We've been focused on the data readouts since that’s really often the most important question that investors have. So we have a Phase 2a program in Graves' ophthalmopathy where we expect data in the first quarter of 2020. Our Phase 2a study in myasthenia gravis, we expect data in the second quarter of 2020. Then we're just about to submit our IND for warm autoimmune hemolytic anemia and we expect the results from that Phase 2a program to be available in the second half of 2020. Then we have a larger Phase 2b program in Graves' ophthalmopathy, a placebo-controlled study that we expect to readout in the first part of 2021.

Sam Slutsky:

Cool. Thanks for that.

Dr. Pete Salzmann:

Yes.

Operator:

Thank you. Ladies and gentlemen, this concludes our question-and-answer session. I'll turn the floor back to Dr. Salzmann for any final comments.

Dr. Pete Salzmann:

Thanks, Melissa. Well, I appreciate all the questions. This is a very exciting space. I think as I mentioned, both in the prepared comments as well as in some of the responses to questions, there's a lot of unmet need and a lot of opportunity both for patients and for what 1401 can achieve in the marketplace. We're really excited about that and I look forward to further dialogue with all of you going forward.

Operator:

Thank you. This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.