

Asterias Biotherapeutics, Inc.
Form 425
November 09, 2018

FILED BY BIOTIME, INC.

PURSUANT TO RULE 425 UNDER THE SECURITIES ACT OF 1933

AND DEEMED FILED PURSUANT TO RULE 14a-12

UNDER THE SECURITIES EXCHANGE ACT OF 1934

SUBJECT COMPANY: ASTERIAS BIOTHERAPEUTICS, INC.

COMMISSION FILE NO.: 001-36646

BioTime Third Quarter 2018 Financial Results Conference Call

November 8, 2018

OPERATOR

Welcome to the BioTime Inc. Third Quarter 2018 Conference Call. At this time, all participants are in a listen-only mode. An audio webcast of this call is available on the Investors Section of BioTime's website at www.biotimeinc.com. This call is subject to copyright property of BioTime Inc. and recordings, reproduction or transmission of this call without the expressed written consent of BioTime is strictly prohibited. As a reminder, today's call is being recorded.

I would now like to introduce your host for today's conference, Ioana Hone of BioTime Investor Relations. Ms. Hone, please go ahead.

Good morning and thank you for joining us. My name is Ioana Hone and I am responsible for investor relations at BioTime and it is a pleasure to be with you today.

A press release reporting our third quarter 2018 financial results was issued earlier today, November 8th, 2018 and can be found on the investors section of our website.

Please note that today's conference call and webcast will contain forward-looking statements within the meaning of federal securities laws including statements regarding our strategy, goals, product candidates, clinical trials, synergies and benefits of the acquisition and financing matters. Such statements are subject to significant risks and uncertainties, including those described in our press release issued on November 8th, 2018, and our recent SEC filings on Form 8-K, Form 10-K and Form 10-Q. Actual results or performance may differ materially from the expectations indicated by our forward-looking statements due to those risks and uncertainties described in the BioTime's and Asterias' reports filed with the SEC, including the following factors: whether our respective shareholders will approve the Merger; the ability to meet closing conditions to the Merger, on a timely basis or at all; delay in closing the Merger; the ultimate outcome and results of integrating the operations of BioTime and Asterias and the ultimate ability to realize synergies and other benefits; business disruption following the Merger; the availability and access, in general, of funds to fund operations and necessary capital expenditures. We caution you not to place undue reliance on any of the forward-looking statements, which speak only as of today. Joining us today are:

Our newly-appointed Chief Executive Officer Brian Culley, our Chief Financial Officer, Russell Skibsted, and our Senior Vice President of Clinical and Medical Affairs, Gary Hogge.

The executives will provide prepared remarks, then take questions from analysts and institutional holders.

With that, I would like to turn the call over to Brian Culley, who joined BioTime as its new CEO on September 17th.

Thank you, Ioana, and good morning, everyone. We have a lot of important items to update for you today, so thank you for joining the call.

To start off, I'm extremely pleased to have been selected by the BioTime Board of Directors to lead the next phase of our growth. I have joined at what I believe is a transformational period for this Company. We aim to become the "Premier Cell Therapy Company" and I believe we have the opportunity to do this, by being one of the first cell therapy companies to turn ambitious research ideas into treatment realities. I want BioTime to lead this mission and I believe I can help drive the process through my experience building the teams, infrastructure, and institutional awareness necessary to advance a pipeline of treatments through clinical development. I also have a successful history of engagement with patient and advocacy groups, which can further increase our visibility and significance within the medical and investment communities by ensuring awareness and appreciation of our clinical accomplishments.

Some of you are aware of my background, so I will just mention that I have a more than 25 years of technical and business experience across diverse operational areas including strategy, finance, product licensing, and product development. Early in my career, I worked at the bench, running experiments at both academic and for-profit research laboratories, so I understand the process and the potential of basic research, but I also spent time in the regulatory world and know what it takes to successfully file a New Drug Application with the FDA. I have a strong business development background and have bought and sold not only individual drug programs, but also several companies.

To give you a sense for my management style, as a former scientist, I believe in making decisions based on reliable data rather than gut feel. As a businessman, I believe in intelligent and disciplined allocation of capital. And as a leader, I believe in focusing on aggressive, but achievable goals. Day-to-day, I am most excited by clinical development and no doubt, as we proceed together, you will see my passion for clinical development reflected in our priorities and by our accomplishments. Lastly, I strive to be an advocate for the treatments I work on and for the patients we serve. I also like to share my enthusiasm, which is helpful if you're trying to generate awareness and build a positive brand for your company. It's a privilege to be here at BioTime and I'm ready to get to work for you and with you.

Although we have important corporate development items to review today, most notably the execution of the merger agreement for the acquisition of Asterias, I believe our product candidates are the ultimate drivers of our value, so I'd like to start off with an update on OpRegen and Renevia before moving on to our recent news on Asterias, AgeX, and Juvenescence.

OpRegen is an allogeneic, or off-the-shelf, cell therapy treatment in development for dry form age-related macular degeneration, the leading cause of adult blindness in the developed world. There currently is no FDA-approved treatment for dry AMD.

Our approach with OpRegen is to grow and deliver healthy RPE cells to the back of the eye where they can replace dead, dying, or dysfunctional RPE cells. We believe this approach can slow the loss of vision and possibly improve vision in affected patients. OpRegen has been granted Fast Track designation by the Food and Drug Administration and currently is the subject of a Phase I/IIa multicenter clinical trial.

This clinical trial is designed first and foremost to evaluate the safety and tolerability of different doses of OpRegen administered to people with dry-AMD, but we also are collecting markers of efficacy in this study, which will help inform our decisions and strategy for the next trial. The current study is expected to enroll a total of 24 subjects and those subjects are divided into four cohorts according to disease stage or severity and as reflected by their visual acuity. We currently are dosing patients in the fourth and final cohort.

We announced new data from this study a couple of weeks ago at the American Academy of Ophthalmology Annual Meeting. The data we shared showed that treatment with OpRegen® continues to be well-tolerated with signs of structural improvement in the retina and decreases in drusen density observed in some patients. As a reminder, RPE cells have multiple functions, including support of photoreceptor maturation, function, and maintenance, so it takes many months following an OpRegen administration for structural-anatomical changes to impact functional recovery and reveal the improved visual acuity that we're looking for, but nevertheless, the early data we've collected from patients in Cohort 4 appears to be encouraging; we can identify signs of structural improvement within the retina, evidence of the continued presence of transplanted cells, and there are even early suggestions of improvements in visual acuity. These data are important to us because Cohort 4 patients have earlier-stage AMD and better vision than Cohorts 1 through 3, so they more closely represent the large patient population we ultimately hope to treat. At the same time, although we're encouraged by these data, these folks do have some vision remaining and we have reported on a few serious but not unexpected adverse events, so enrollment is proceeding slowly to ensure we are providing a compelling risk-reward benefit, which ultimately is how the FDA will assess the program. But nonetheless, the trial is expected to complete enrolling early next year and we expect the data from this study will support faster enrollment in our next clinical trial.

Turning next to Renevia, our medical aesthetics program, we have three points to make. First, we submitted our CE Mark application this year to BSI, the independent accredited body in the UK responsible for reviewing such applications. This review is ongoing with responses to BSI's questions being promptly provided by BioTime. It is important to note that the regulatory review process does not come with a statutory clock, meaning BSI can take as long as necessary to review our application. But once the review is completed, BSI will notify us of their feedback. Our best estimate at this time for a response is early next year.

Second, we have a similar wait-and-see situation in the U.S. We do not yet fully know how Renevia will be classified by the FDA. If it's viewed as a device, as in Europe, that is a favorable outcome and may afford a relatively rapid development path. But if it is considered to be a drug or biologic, or as a combination product under the jurisdiction of CBER, presumably attributable to hyaluronic acid or the use of a patient's own fat or cells, then we would be facing a decision to undertake a far longer and significantly less attractive product development path.

Thirdly, the initial data using large-volume administrations have not been as robust or as well-tolerated as those which were reported to us with small volume treatments. There are some significant differences between the two studies and only a handful of treatments have occurred to date, but because there's a precedent for large-volume fillers not to perform as well as their smaller equivalent doses, and because we also have all this regulatory uncertainty which I just described and which likely won't read out until next year, we plan to reduce our clinical and regulatory activities with Renevia until we have more clarity as to our regulatory and commercial options.

Depending on the outcomes from the three items I just mentioned, which span from product approval down to further development, or just seeking a partner for the program, I really don't want to get too far ahead of myself on this call, but putting a business development effort behind Renevia might make a lot of sense in light of our recent acquisition.

That's actually a convenient segue to the first of several corporate development events we plan to discuss. First, I'm extremely pleased to share that we have entered into a definitive merger agreement, through which BioTime will acquire all of the remaining outstanding common stock of Asterias Biotherapeutics not currently owed by BioTime, which upon closing will become a wholly-owned subsidiary of BioTime, if closing conditions are met, including approval by our respective shareholders. The acquisition is expected to provide several important and positive benefits for us.

First, we believe their cell therapy product candidates fit *naturally and operationally* within BioTime's existing portfolio.

Second, we already are the largest shareholder of Asterias, so we only needed to issue enough shares to acquire the approximately two-thirds of the company which we don't already own.

Third, we have unique cell manufacturing expertise at our GMP facility in Israel and a broad patent position, which together we believe can help accelerate their product development and commercialization timelines.

And Fourth, we expect to benefit from certain financial synergies and enjoy other advantages from our critical mass, which collectively supported our decision to merge the pipelines and create a dominant cell therapy company.

Our vision is to build BioTime into a pioneering leader in cell therapy and this acquisition can help make that a reality because it not only diversifies our pipeline with clinical assets addressing high unmet medical needs, but also adds partnerships with notable and relevant institutions such as the California Institute for Regenerative Medicine and Cancer Research UK. We believe this merger can be an opportunity for BioTime's stockholders to benefit from the current and future value of a broader pipeline as well as the opportunity to meaningfully impact disease areas that are in desperate need of innovative therapeutic approaches and which seem like suitable targets for whole-cell approaches, rather than small molecule or antibody-based modalities. As part of our ambition to become the Premier Cell Therapy Company, we want to be ahead of the curve. We believe the next big biotech breakthrough will be in cell and gene therapies. For some recent evidence, I would point to strategic moves from companies like Novartis, Astellas, and Novo Nordisk, each of which has announced significant commitments to cell and gene therapies in just the past few weeks.

I won't go into a lot of detail on the Asterias pipeline today, but just to orient you a bit, it features OPC1, an innovative, whole-cell approach to treating Spinal Cord Injury, and which is the subject of a phase 1-2 clinical trial which recently completed its enrollment.

OPC1 is a cellular therapy which utilizes oligodendrocyte progenitor cells to address the complex pathologies observed in demyelination disorders, such as a spinal cord injury or neurodegenerative diseases like multiple sclerosis and white matter stroke. The potential reparative functions of OPC1 include the production of neurotrophic factors, the stimulation of vascularization, and the induction of remyelination of denuded axons, all of which are critical for survival, regrowth, and conduction of nerve impulses through axons at the injury site.

Patient enrollment and dosing in cervical spinal cord injury is complete in a Phase 1/2a study called SCiStar. The current study and other earlier work with OPC1 suggested a favorable safety profile regarding OPC1 itself and the procedure used to administer the cells to patients. The data from the current study also has shown durable engraftment of the OPC1 cells at the injury site in over 95% of patients treated. Patients in the trial are quadriplegics as a result of their cervical spinal cord injuries, yet many of them are showing promising motor recovery in their fingers, hands, and arms. There have been no serious adverse events observed attributable to the OPC1 cells. There were two serious adverse events, one of which was associated with the injection procedure and the other was related to the immunosuppression regimen. While many of the patients in the SCiStar Study have shown promising upper extremity motor recovery, the extent of the recovery attributable to OPC1 and not spontaneous recovery will need to be evaluated as part of a randomized controlled trial. Although the twelve-month results from the SCiStar study are anticipated in Q1 next year, an Independent Data Review Panel for the study met last month and recommended the continued clinical development of OPC1, which we of course intend to continue after the close of the acquisition. In fact, a Type B meeting with the FDA, in accordance with the Regenerative Medicine Advanced Therapy or RMAT designation Asterias received, has already been scheduled.

Notably, this program has been partially funded by the California Institute for Regenerative Medicine, or CIRM, and we believe it has the potential to obtain additional non-dilutive funding to partially offset the cost of OPC1's next phase of clinical development.

The second clinical-stage asset we will acquire through this deal is called "VAC", a cell therapy immuno-oncology platform, which as we all know is a hot area for drug development.

VAC is a form of immunotherapy which aims to stimulate the body's ability to recognize cancer antigens and mount an immune response to control the spread of disease. Dendritic cells direct the function of the immune system through the presentation of antigens, and they can be harnessed as therapeutic agents. Asterias' dendritic cell-based vaccines target a protein expressed in over 95 percent of cancers, but which is rarely found in normal adult cells. VAC1, for Acute Myeloid Leukemia, or AML, is an autologous vaccine, based on cells sourced from the specific patient, while VAC2 is an allogeneic, or non-patient specific vaccine, manufactured from a pluripotent cell platform and which is being developed to treat non-small cell lung cancer or NSCLC. Notably, this platform was designed to be synergistic with other therapies currently in development for these indications, including new chemotherapeutics or other immunotherapy approaches, such as immune checkpoint inhibitors.

The VAC1 results from the Phase 2, multi-center open label clinical trial in AML which met the primary safety endpoint, serves primarily as an encouraging proof of concept for the VAC2 program.

The main initiative, VAC2, is a Phase 2 program which enjoys a valuable partnership with Cancer Research UK, the world's largest independent cancer research charity. Cancer Research UK provides substantially all of the funding for the current clinical trial, so this study is not anticipated to add a significant amount of expense to the combined company's budget.

In July of this year, the Safety Review Committee for the phase 2 study reviewed the available safety and tolerability data and recommended continuation of the study and moving to parallel enrollment of additional patients in the advanced cancer cohort, per the study's protocol.

Speaking next about the structure of the proposed merger, following the closing, the holders of Asterias' outstanding capital stock will receive 0.71 common shares of BioTime for every share of common stock of Asterias they hold. On a pro forma and fully-diluted basis, Asterias shareholders are expected to own approximately 16% of the merged company and BioTime shareholders are expected to own approximately 84% of the merged company.

The proposed merger has been approved by the board of directors of each company acting upon a recommendation of a special committee of the board of each company, and is expected to close during the first quarter of 2019, subject to approval of the transaction by the shareholders of both companies and other customary closing conditions.

From a general management perspective, we anticipate a smooth transition and integration process. According to the merger agreement, two members of the current Asterias Board of Directors will be represented on the BioTime Board of Directors, one of whom (Don Bailey) will be a new addition as of the effective time of the merger and the other of whom (Michael Mulroy) already serves on the BioTime Board. Dr. Ed Wirth, who many of you know as Asterias' Chief Medical Officer, will continue to lead the OPC-1 program.

From my perspective, I'm excited to manage a larger and more important portfolio of related assets. I've previously led the acquisition of three companies and I'm grateful that the close relationship we've had with Asterias means this business combination does not appear to pose any unusual challenges for us. After closing the acquisition, I look forward to collaborating closely with Mike Mulroy, the Asterias CEO, on the integration process to ensure it is rapid, disciplined, and productive for our shareholders.

Next I'd like to discuss AgeX Therapeutics. Keeping in mind that BioTime owns an extensive portfolio of patents and related technologies, it is impossible for us to develop everything we own into a commercial product or technology. For this reason, AgeX was created as a basket of early-stage, non-core assets and research programs, to be separately funded and developed. We then convert them into non-equity dilutive cash for our core operations. In this particular and I believe, highly successful example, the assets are focused on the biology of aging and age-related diseases, which is an area of increasing interest, evidenced by the emergence of companies such as Calico and Juvenescence. Selling half of our interest in AgeX to Juvenescence and distributing most of the remainder to our shareholders is a great example of our ability to unlock value from our platform to provide capital and focus on our core assets. And as you will have seen a few days ago, we just received the second installment of \$10.8 million dollars from that sale. We also recently announced a record date of November 16th and distribution date of November 28th for the distribution of AgeX shares, at which point AgeX will become a separately traded public biotech company. Although we will separate BioTime's research and development operations from AgeX, we certainly will retain a positive and active relationship with the company, including of course with BioTime's former CEO, Dr. Mike West who has been very helpful to my on-boarding process. We also will enjoy a 4.9 percent ownership in AgeX, which we can elect to sell in the open market for cash or retain longer-term, as potential upside from the success of AgeX and Juvenescence.

Speaking of Juvenescence, I mentioned a moment ago that we received earlier this week a cash payment of \$10.8 million dollars representing the second installment from the sale of approximately 50% of our interest in AgeX to Juvenescence. We now have received 50% of the total purchase price and we expect to receive the remainder of the \$43 million dollar purchase, that being approximately 21 million additional dollars, upon the maturity of the convertible note we provided to Juvenescence at closing. And as has been stated on a prior call, that note can be converted into shares of Juvenescence, so depending upon how their planned IPO performs, it's possible we could receive significantly more than just \$21 million in principal. For many reasons, strategic and economic, we're hopeful they will have a highly successful IPO sometime next year.

That seems like plenty of information on our clinical programs and corporate development efforts, so I'll now turn the call over to Russell to review our financials for the third quarter. Russell? Thanks Brian.

BioTime's consolidated cash, cash equivalents, and marketable securities totaled approximately \$21.4 million-dollars as of September 30, which compared to approximately \$29-million-dollars as of the end of the second quarter, at which time we consolidated AgeX's financials.

As Brian noted a moment ago, we received the second installment of \$10.8-million-dollars from the Juvenescence transaction.

In addition, we own publicly-traded common stock in Asterias and OncoCyte, which represent an aggregate market value of approximately \$53-million-dollars.

Once the planned distribution of AgeX is completed later this month, we will own over 1.7 million shares. In upcoming financials, the value of these shares will be included on our balance sheet as marketable securities.

We also have a \$21.6 million dollar convertible note from the Juvenescence transaction which we received during the 3rd quarter. If this note is converted to Juvenescence common stock prior to its maturity date, due to a Juvenescence IPO, the value of the common stock may also be categorized as a marketable security that BioTime may use to supplement its liquidity. If the Juvenescence note is not converted, it is payable in cash, plus accrued interest at 7% per year, at maturity.

As a reminder, as a result of the sale of 50% of our interest in AgeX to Juvenescence, we deconsolidated AgeX's financials from ours on August 30, 2018. So going forward, our operating results will no longer include AgeX's operating results. In the meantime, to provide additional clarity as to BioTime and AgeX's financials, we've included a non-GAAP table at the end of our earnings release that details operating expenses by entity, adjusted for non-cash expenses. We believe this will help investors better understand both BioTime's and AgeX's financials, which we believe will make our story more straightforward for investors.

Please keep in mind when reviewing this table, that the table is not a cash-flow by entity because grants and other revenues are not included in the operating expenses.

During the quarter, BioTime's consolidated NON-GAAP operating expenses, after eliminating non-cash items, were 8.8-million-dollars, which is comprised of about 7.4-million-dollars for BioTime and about 1.4-million-dollars for AgeX. The \$7.4 million dollar for BioTime includes about \$1.5 million dollars of non-recurring expenses. Grant revenue of about 718 thousand-dollars was recognized by BioTime during the quarter. BioTime's actual cash burn for the quarter is in line with our prior guidance.

Moving now to details of the distribution of AgeX shares. We plan to distribute approximately 12.7 million shares to BioTime shareholders of record, as of the Record Date, on November 28. If you own shares of BioTime as of the close of trading on November 16, which is the Record Date, you will receive 1 share of AgeX for every 10 shares of BioTime you own.

To be clear, this is not an exchange of one company's stock for another. Think of it more like a stock dividend, but a dividend in the form of stock in a newly-public company. Please note that BioTime shareholders will not be required to take any action in order to receive the AgeX distribution, meaning they will not have to surrender or exchange BioTime common shares in order to receive their new AgeX shares.

The distribution of shares will ensure that AgeX has a large shareholder base on its first trading day.

To reiterate, The Record Date is the date, which the list of BioTime shareholders eligible for the distribution is set, is scheduled for November 16, 2018. The distribution of the AgeX shares themselves is planned for November 28, 2018.

After the Record Date, BioTime shares will trade with "Due-Bills" attached, which means that if you sell your BioTime share after the Record Date, you are also selling your right to receive the distribution of AgeX shares. Likewise, if you buy shares of BioTime after the Record Date, you will also be buying the sellers' right to receive the distribution.

For details around the mechanics for receiving shares in the distribution as a BioTime shareholder, please refer to the Registration Statement on Form 10 that AgeX has filed with the SEC, accessible on the SEC's website at www.sec.gov. It is important to bear in mind that, under current expected timetables, Asterias shareholders are not expected to participate in the AgeX distribution, as the Asterias merger is expected to close after the distribution is already completed.

And with that, I will turn the call back to Brian.

Thanks, Russell. To conclude, although the overall biotech markets have been volatile recently, we believe a focus on the fundamentals and in particular, the steps we've recently taken to provide for a positive future for BioTime, has provided us with the ability today to report on an exciting and transformative quarter.

We have supplemented and strengthened our pipeline with two additional and synergistic assets, which will help us become a "Premier Cell Therapy Company";

We have strategically converted earlier-stage non-core research programs into cash and equity which can be utilized to fund our more clinically-advanced value drivers without diluting our shareholder's equity; and

We have advanced the clinical development of our lead program, OpRegen, which continues to generate encouraging results in a disease with no currently approved therapies and comparatively modest competition.

This quarter was packed with news, but we have no plans to slow our pace of progress. We plan to complete the Asterias transaction early next year and will integrate the companies in a thoughtful and productive manner. We will remain focused on advancing our clinical programs throughout 2019 and we will update investors often on our new timelines and regulatory plans.

As a final topic for today, I'm confident in our future because I previously transformed companies not only through strategic transactions like those we've discussed today, but also by building institutional and retail relationships through productive and continuous engagement. I have longstanding relationships with the buy-side and sell-side from prior CEO roles and I intend to bring a similar approach to BioTime in order to increase awareness and visibility of the company and our programs.

Awareness is vital to our growth. To highlight that point, we recently restructured our IR function by engaging The Hone Group and Solebury Trout, a global investor relations firm specifically serving the life sciences industry. We will work with these professionals to increase our exposure to the capital markets and accelerate interest in BioTime from the institutional investment community.

Our goal is to build awareness and support for a reinvigorated and repositioned BioTime and have BTX on every investor's radar screen next year.

We will achieve this through numerous initiatives, including:

- A targeted investor outreach, to help build an institutional following;
- Investor and sell-side KOL events, to educate people about our promising science in greater detail;
- Conferences and non-deal roadshows in major cities;
- And an aggressive roll-out of our recent progress and future plans at JP Morgan, the largest healthcare conference of the year;

Importantly, I believe that stating - and then delivering - on our milestones across a spectrum of corporate and clinical development activities ultimately will drive the company forward on both a fundamental and equity basis and that will be this management team's priority and focus.

And with that, operator, we are ready for questions.

Question-and-Answer Session

Operator

[Operator Instructions] And our first question comes from Reni Benjamin with Raymond James. Please proceed.

Reni Benjamin

Hey, thanks for taking the questions. Congratulations Brian on the new role and it seems like you're already beginning to transform the company. So good luck with that. Have a couple of questions, maybe starting off with OpRegen. You did have some updated data, you mentioned during the prepared remarks that enrollment is progressing, you hope to complete enrollment by next year, but just kind of looking out into 2019, can you talk a little bit more about your vision in terms of advancing the OpRegen asset into more pivotal studies, or do you think that you know longer term follow ups from the given - from the current cohorts are what are more likely in that only after discussion with the FDA and possibly in 2020 or so is when the next sort of pivotal studies will be conducted?

Brian Culley

Hey Reni. Thank you very much for the warm welcome. And with respect to OpRegen, I'll let Gary follow-up, but what I would say is that the more data that you bring to the agency obviously the more helpful that is and the more informative it is. I do not believe it is the case that we need to wait 12 months after the last patient dosed to have the clarity and develop our plans and so forth. But let me give Gary an opportunity to provide some more detail around that.

Gary Hogge

Thanks Reni. So, basically as we said recently as at AAO, we enrolled the first 12 patients in cohorts 1, 2, 3 and the first 3 patients in the fourth that are receiving better vision cohort. There is a total target of 12 for that cohort. So as at the day we presented at AAO, we are certainly encouraged by the early data showing the potential size of efficacy and certainly well tolerate at this point. And so as we progress with that better seeing, better vision, this cohorts will feel to better assess how to move forward after that.

Reni Benjamin

Got it. Okay. And then just switching gears to Renevia, can you provide some color a little bit of context regarding the kind of questions that you're getting, you know if you believe that this is likely going to result in approval by the first quarter of 2019, I've seen that there is nothing all that onerous or complicated, but any sort of color regarding that process?

Gary Hogge

Yes, so the question that we received today have been unremarkable standard around CMC that we've been able to easily address what we've been waiting for our questions around the clinical aspect and BSI has new process, they've instituted which has delayed their questions to us. So as soon as those are received, we'll have a better idea of when we might deal with that forward, but I think that is a good assessment if you take Q1 of next year.

Reni Benjamin

Got it. And just regarding the ongoing activities, I think Brian you mentioned that there will be a reduction of the ongoing activities. I assume you mean here in the U.S. and the IS, investigator sponsored studies. Am I correct in that or is there something else?

Brian Culley

No, that's correct. The work is substantially complete and European study and as just was discussed, the regulatory work with respect to the CE Mark is ongoing. So yeah, the wait and see approach the slowdown of activity, that's really looking exclusively at the U.S.

Reni Benjamin

Got it. Okay. And then just finally for me. It seems like just my back to the angle of calculation for the acquisition of the remaining shares of BioTime, I guess total is about \$82 million or so is what the company is being valued at, is that correct or did I miss something?

Brian Culley

With respect to the valuation of the company, I mean you're right and of course that's going to change daily as we trade because we have a fixed conversion ratio. But yeah, they have about 55 million over 55 million shares outstanding.

Remember, we own about 30% or about close to 40% of those, so if you look at a net basis, it ends up being you know roughly 16% that the shareholders will own at BioTime once all of this gets completed. But I think you're back to the envelope calculations today are correct.

Reni Benjamin

Excellent. Thanks very much guys and good luck on going forward.

Brian Culley

Thank you, Reni.

Operator

Thank you. And our next question comes from Keay Nakae with Chardan. Please proceed.

Keay Nakae

Yes, thank you. I am wondering if you can comment on the upcoming meeting with the FDA. And number one, do you have some firm objectives that you're looking to come out of the meeting having gain clarity on and just maybe a more general statement since you've had receive the RMAT designation, do you believe that that's been helpful in your interactions with the agency?

Brian Culley

So, for the U.S. what we're interested in finding out because it has a very significant impact on our future plans is how the agency will categorize or view the product. So, because of the use of cells, because some of the components of Renevia, it may be deemed to be more drug like than device like. And as you are well aware - sorry.

Keay Nakae

Brian, I was referring to OPC1, I'm sorry.

Brian Culley

Pardon me, Keavy. Well here let me - I'll just send it right to Gary.

Gary Hogge

Well, with regards to OPC, so the agency doesn't have to give us response our questions more than 24 hours since we have answered the meeting, so we don't know what the responses are, start inquiries at this time. So once we receive them, we'll have a better idea of whether or not our initial believes based on the data are consistent with what the FDA is.

Keay Nakae

And have you been finding the interaction easier since you've got the RMAT designation?

Brian Culley

That's really a question for Asterias. We have - we're in that period between signing and closing, so it really is something that we can't answer, but obviously we're directed to them until the deal closes and then we can provide abundant information.

Keay Nakae

Okay. And then just moving on to the acquisition. Is there - I know you said a number of reasons for doing it, but would you say there's a primary one, obviously you have the current equity ownership you'd like to protect, you've talked about the synergies and the operation the assets themselves have their own compelling values. But is there a primary driver especially when we consider that they are earlier stage and would require an investor as we have with the serious investors to have you know that longer term investment horizon for those assets?

Brian Culley

Yeah, that's a good question. We didn't apportion a let's say percent contribution of each of the factors that we considered, it's really a constellation of things. But that constellation together is intended to help create a premier cell therapy company. So we think that all the items I won't repeat them because you've already heard them from me, but all of them have a purpose and the purpose is to establish BioTime as that preeminent company. I think we've all been waiting a very long time for the promises of cell therapy to become reality. And so having the critical mass to having multiple shots on target, going after programs that I believe are more suitable with respect to wholesale approaches. All of these things together are intended to achieve that objective and each of them contribute an important way.

Keay Nakae

Okay, thanks. That's all I have.

Brian Culley

Great, thanks Keay.

Operator

Thank you. And our next question comes from Jason McCarthy with Maxim Group. Please proceed.

Jason McCarthy

Hey guys and I'd also say congratulations Brian on your new role, looking forward to where BioTime is going to go over the next year, very exciting in cell therapy. Question around manufacturing, you did mention that you have that GMP facility in Israel and I was wondering you know what's the capacity of that facility, manufacturing become a bit of a hot topic around things like gene therapy and now that you have the Asterias assets coming under the BioTime. Will you look to transfer that manufacturing in-house to your own facility?

Brian Culley

Yeah, that's an excellent point. I think people occasionally lose sight of the fact that cell therapy manufacturing is a little bit different and very difficult and reproducibility and control have tripped up some companies. I've only been on the job 7 weeks, I'm actually headed to go see, I'm going to go to Israel and see our facility leaving on Sunday. So I'm going to get a sense for that. We haven't made any final decisions about where any assets are going to be manufactured, we have ideas and plans. Certainly we will update you on a full some way after closing. But with respect to sort of faction figures around that facility, I invite Gary if he has anything to add to it. We have been able to manufacture plenty of OpRegen more than is necessary for our next study. So I think we're in good shape there but expect to additional capacity in the potential to move other assets there.

Gary Hogge

I will echo Brian's comments. So certainly we are comfortable with production for OpRegen and remains, we've seen what we do with other assets.

Jason McCarthy

Okay. And in terms of OPC1, you mentioned some features of the SCi-STAR study, can you tell us when the next update from that program is going to be, is that would assume that with spinal cord injury that this is going to need or require long term looks at efficacy even without having a randomized trial, this initial just to see if those effects are maintained?

Brian Culley

I wish I could. Again I could only refer you to the comments I made already on the call. We're not allowed to provide guidance with respect to the proposed merger. So I'm going to have to defer that redirect you to Asterias themselves until at such time the deal is closed.

Jason McCarthy

Okay, great. Thanks for taking the question. Congratulations again.

Brian Culley

Thank you very much Jason.

Operator

Thank you. And at this time I'm showing no questions in queue. I like to turn the call back over to Brian Culley for further remarks.

Brian Culley

All right, so in just the past two weeks, we've announced the acquisition of one public company and the distribution date for another. We've announced the receipt of \$10 million of non-dilutive capital and encouraging clinical data in a disease with no treatment options. So I'm feeling pretty good about my first conference call at BioTime. I appreciate everyone joining us this morning. I'm excited about our plans. And I hope we'll be able to keep this positive momentum going for a long time. Thanks very much.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program, you may now disconnect. Everyone have a great day.

Additional Information and Where to Find It

This communication is being made in respect of the proposed business combination involving BioTime, Inc. and Asterias Biotherapeutics, Inc. In connection with the proposed transaction, BioTime and Asterias plan to file documents with the U.S. Securities and Exchange Commission (the "SEC"), including the filing by BioTime of a Registration Statement on Form S-4 containing a Joint Proxy Statement/Prospectus and each of BioTime and Asterias plan to file with the SEC other documents regarding the proposed transaction. **INVESTORS AND SECURITY HOLDERS OF BIOTIME AND ASTERIAS ARE URGED TO CAREFULLY READ THE JOINT PROXY STATEMENT/PROSPECTUS (WHEN AVAILABLE) AND OTHER DOCUMENTS FILED WITH THE SEC BY BIOTIME AND ASTERIAS BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.** Investors and security holders may obtain free copies of these documents (when they are available) and other documents filed with the SEC at the SEC's web site at www.sec.gov and by contacting BioTime Investor Relations at (510) 871-4188 or Asterias Investor Relations at (510) 456-3892. Investors and security holders may obtain free copies of the documents filed with the SEC on BioTime's website at www.biotimeinc.com or Asterias' website at www.asteriasbiotherapeutics.com or the SEC's website at www.sec.gov.

BioTime, Asterias and their respective directors and executive officers may be deemed participants in the solicitation of proxies with respect to the proposed transaction. Information regarding the interests of these directors and executive officers in the proposed transaction will be included in the Joint Proxy Statement/Prospectus described above. Additional information regarding the directors and executive officers of BioTime is also included in BioTime's proxy statement for its 2018 Annual Meeting of Shareholders, which was filed with the SEC on March 29, 2018, and additional information regarding the directors and executive officers of Asterias is also included in Asterias' proxy statement for its 2018 Annual Meeting of Stockholders, which was filed with the SEC on April 30, 2018, respectively.

No Offer or Solicitation

This document does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Forward-Looking Statements

Certain statements in this communication, including statements relating to the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement and the combined company's future financial condition performance and operating results, strategy and plans, including the design, status, funding and timing of the clinical trials and further development and potential of the product candidates are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 giving BioTime's and Asterias' expectations or predictions of future financial or business performance or conditions. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time. Forward-looking statements speak only as of the date they are made and we assume no duty to update forward-looking statements. In addition to factors previously disclosed in BioTime's and Asterias' reports filed with the SEC and those identified elsewhere in this communication, the following factors, among others, could cause actual results to differ materially from forward-looking statements and historical performance: the ability to meet closing conditions to the Merger, including requisite approval by BioTime's and Asterias' stockholders, on a timely basis or at all; delay in closing the Merger; the ultimate outcome and results of integrating the operations of BioTime and Asterias and the ultimate ability to realize synergies and other benefits; business disruption following the Merger; the availability and access, in general, of funds to fund operations and necessary capital expenditures. More information on potential factors that could affect our results is included from time to time in the SEC filings and reports of BioTime and Asterias, including the risks identified under the sections captioned "Risk Factors" in BioTime's quarterly report on Form 10-Q filed with the SEC on November 8 and Asterias' annual report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018, and Asterias' quarterly report on Form 10-Q for the quarter ended September 30, 2018, which Asterias expects to file on November 9, 2018.

BioTime Inc. IR

Ioana C. Hone

ir@biotimeinc.com

(510) 871-4188

Solebury Trout IR

Gitanjali Jain Ogawa

Gogawa@troutgroup.com

(646) 378-2949

Asterias Biotherapeutics IR

Investor Relations

(510) 456-3892

InvestorRelations@asteriasbio.com

EVC Group LLC

Michael Polyviou

mpolyviou@evcgroup.com

732-232-6914

