VIAVID
communications simplified.

Can-Fite BioPharma, Ltd.

Q2 Results and Business Update

August 27, 2020

CORPORATE PARTICIPANTS

Pnina Fishman, Ph.D., *Chief Executive Officer*

Motti Farbstein, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Jason Kolbert, *Dawson James*

Vernon Bernardino, *H.C. Wainwright*

PRESENTATION

Operator

Good afternoon everyone, and thank you for joining Can-Fite's Second Quarter 2020 Conference Call.

Today, the Company will provide a financial update for the quarter ended June 30, 2020, as well as the latest developments in the Can-Fite advanced stage clinical pipeline.

On the call today are Can-Fite's CEO, Dr. Pnina Fishman, and the Company's CFO, Motti Farbstein.

At the end of the call, we will have a question-and-answer session.

We will start a brief Safe Harbor statement. This conference call may contain forward-looking statements about Can-Fite's expectations, beliefs or intentions regarding, among other things, market risk and uncertainty, its product development effort, business financial condition, results of operation, strategies or prospects. Forward-looking statements can be identified by the use of the forward-looking words, such as *believe, expect, intend, plan, may, should* or *anticipate*, or their negatives, or other variations of these words, or other comparable words, or by the fact that these statements do not relate strictly to historical or current matters. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risk and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Now, I would like to turn the call over to Dr. Pnina Fishman. Thank you, you may begin.

Pnina Fishman, Ph.D.

Thank you (inaudible) and thanks all of you for participating in our call today.

In clinical developments for our advanced pipeline of small molecule drugs during the second quarter, include the final data analysis from our Phase 2 NASH study, which showed that namodenoson-treated

patients had a highly significant and sustained reduction in liver fat volume throughout the study period. Namodenoson also moved one step closer to its Phase 3 global pivotal trial in liver cancer, following successful meetings and guidance from both agencies, the FDA in the U.S. and the EMA in Europe.

Our lead drug candidate piclidenoson is headed into a Phase 2 COVID-19 study in the U.S. and Israel, as we await the response of the SVA to our submitted IND.

We are highly encouraged by all these important developments, and now I would really get into further details about these and other clinical developments.

As we reported in June, our successful Phase 2 study of namodenoson in NAFLD NASH produced even more positive and meaningful data upon final analysis. While incidence of NAFLD NASH continue to rise, there is still no treatment for this condition, which is expected to soon surpass hepatitis C as the leading cause of liver transplants in the U.S.

An estimated 25% of U.S. adults is NAFLD and 20% of those have NASH, according to the American Liver Foundation.

While a handful companies have taken their drugs into advanced-stage trials for the treatment of NASH, those that have completed pivotal-stage studies have not yet succeeded in showing both safety and efficacy sufficient to support marketing approval, according to health regulatory agencies. This underscores the continued need for a variety of NASH drugs that are both safe and effective to address a very large and unmet need.

Namodenoson has been evaluated in the Phase 2 studies for both NASH and liver cancer, with both studies showing a very favorable safety profile and lack of hepatotoxicity.

As reported previously, namodenoson induced significant change in primary and secondary study endpoints over the 12-week study period, which is a very relatively short period of time.

A robust anti-inflammatory effect manifested by a significant decrease in the liver enzymes ALT and AST and a significant improvement in the positive cytokine adiponectin was recorded.

A reduced liver fat content and a reduction in percent of liver fat volume was found together with a decrease in FIB4 and FAST, both non-invasive tests used as markers to exclude advanced fibrosis.

In addition, a decreasing burden rate has been observed in the two doses of namodenoson, with a better effect in the higher dose. The 25 milligram dose of namodenoson was found to have optimal efficacy, while also having a strong safety profile, and was well tolerated. Twenty-five mg has been selected as the dose to be used in our next NAFLD NASH study.

We believe namodenoson is a very strong candidate for continued clinical development in the treatment of NAFLD NASH, and we are now working closely with key opinion leaders on the development of our next clinical study in this indication.

We were very pleased that during the second quarter the U.S. Patent and Trademark Office granted to Can-Fite a patent for namodenoson in the treatment of NAFLD NASH. Additionally, just a few days ago, we were notified by the European Patent Office with the intent to issue a similar NAFLD NASH patent to us. Earlier in the year, we issued a patent in this indication in Korea. This is very important for us since we have already signed an out-licensing deal in Korea. Our global intellectual property portfolio addressing NAFLD NASH is critical as we engage in talks with potential distribution partners.

Namodenoson has also shown significant efficacy in the treatment of liver cancer in the population defined as Child-Pugh B, which constitutes 70% of the patient with advanced liver cancer.

Now, I will provide an update on our planned pivotal global Phase 3 study of namodenoson in this indication. Our aim is to conduct one Phase 3 pivotal trial in the U.S., Europe and Israel for regulatory approval in those markets, should the study achieve its endpoint.

As previously announced, following a successful End-of-Phase 2 meeting with the FDA regarding namodenoson in the treatment of advanced hepatocellular carcinoma, the FDA agreed with us proposed pivotal Phase 3 trial design to support a New Drug Application submission and approval. During the second quarter, we also concluded a successful meeting with the European Medicine Agency Scientific Advice Working Party regarding this same Phase 3 protocol. Based on advice from both regulators and our academic key opinion leaders, we have completed our protocol for the pivotal Phase 3 study designed to support a New Drug Application submission in the U.S. and a Marketing Authorization Application in Europe.

Now I will turn to developments with piclidenoson.

We filed an Investigational New Drug Application with the FDA for piclidenoson in the treatment of COVID-19. Piclidenoson's anti-rheumatic and anti-viral effects, combined with its excellent safety profile, make it a potential candidate for the treatment of coronavirus.

Based on pre-IND advice and guidance we received from the FDA during the second quarter, towards end of July we filed an IND for planned 28-day Phase 2 study to evaluate hospitalized patients with moderate COVID-19 symptoms. The randomized double-blind placebo-controlled trial will enroll 40 patients who are receiving standard supportive care, and will be randomly assigned in a 1:1 ratio to the trial arm of piclidenoson twice daily or placebo. After 28 days of treatment, efficacy will be assessed through standard measures of clinical and respiratory status at day 29, including the proportion of patients alive and free of respiratory failure, as well as the proportion discharged home without need of supplemented oxygen. We are working with FDA's Coronavirus Treatment Acceleration Program and expect IND activation very shortly to begin our Phase 2 trial.

Piclidenoson has completed over 50% enrollment in two Phase 3 studies for rheumatoid arthritis and psoriasis, and we expect an interim data readout in the fourth quarter, data monitored by two independent data monitoring committees, which will have an unblinded access to the data during the third quarter, and we intend to announce this data in the fourth quarter.

Following the end of second quarter, we achieved a milestone in our cannabinoids program as well. We completed the development of a biological cell-based in vitro assay which can identify clinically active cannabis-derived compounds that bind to and activate A3 adenosine receptor, the target of Can-Fite's platform technology. Studies published in peer-reviewed scientific journals demonstrate that cannabis-derived compounds bind to the Gi protein-coupled A3 adenosine receptor, which is over-expressed in pathological cells and tissues. In addition to using this assay in the development of our own cannabis-derived compound-based therapeutics, we also plans to market the assay on a fee-for-service basis to researchers and other cannabis companies worldwide.

I will now turn the call over to Motti Farbstein, our CFO, for a review on the financial results. Motti please.

Motti Farbstein

Thank you Pnina.

Revenues for the six months ended June 30, 2020 were $0.4 million, compared to the revenues of $0.68 million during the six months ended June 30, ’19. The decrease in the revenues was mainly due to the recognition of lower portion of advance payments received under distribution agreement from Gebro, CKD Pharmaceuticals and Cipher Pharmaceuticals.

Research and development expenses for the six months ended June 30, 2020 were $7.05 million, compared with $3.96 million for the same period in ’19. Research and development expenses for the six months ended June 30, 2020 compromised primarily of expenses associated with Phase 2 studies for namodenoson in the treatment of NASH and HCC, as well as expenses for ongoing Phase 3 studies of piclidenoson in the treatment of rheumatoid arthritis and psoriasis. The increase is primarily due to the increased costs associated with the accelerating rate of enrollment of patients for the Phase 3 clinical trials of piclidenoson for the treatment of rheumatoid arthritis and for the psoriasis study.

General and administrative expenses were $1.45 million for the six months ended June 30, 2020 compared to $1.33 million for the same period in ’19. The increase is primarily due to an increase in compensation-related benefits and insurance expenses which was partly offset by decrease in travel expenses and professional services.

Financial expenses net for the six months ended June 30, 2020 was $0.12 million, compared to financial expenses net of $0.28 million for the same period in ’19. The decrease in financial expenses net is primarily due to a decrease in exchange rate expenses.

Can-Fite's net loss for the six months ended June 30, 2020 was $8.23 million, compared with net loss of $4.89 million for the same period in ’19.

As of June 30, 2020, Can-Fite had cash and cash equivalent of $9.05 million, as compared to $2.69 million at December 31, ’19. The increase in cash during the six months ended June 30, 2020 is due to an aggregate of $17.9 million received through a warrant exercise transaction in January 2020, a public offering in February 2020, partial exercise in March–April 2020, a public offering in February 2020, partial exercise in March, April and May 2020 of warrants issued in February 2020 public offering, and a registered direct offering in June 2020.

I will now turn the call over to the Operator for our Q&A session.

Operator

Thank you. At this time, we will be conducting a question-and-answer session. If you would 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 would 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 keys. One moment please as we poll for questions.

Our first question comes from the line of Jason Kolbert with Dawson James. Please proceed with your question.

Jason Kolbert

Shalom guys, how are you doing?

Pnina Fishman, Ph.D.

Thank you, I'm good.

Jason Kolbert

Okay. In terms of COVID, can you walk me through what you're thinking in terms of the effect that you might see and that you might use in order to kind of explore a trial, a Phase 1 trial, and what dose and dosing, and most importantly at what point would you expect to be able to administer the drug? Because our understanding of the disease is that, once people are hospitalized, they're experiencing the cytokine storm, if you will; and so one goal is deleting the virus, another goal is reducing the inflammation, all of which without interfering with the body's ability to heal itself. So, steroids are a blunt instrument; are you from a mechanism of action point of view looking at this as a more specific instrument versus a steroid? Thanks.

Pnina Fishman, Ph.D.

Okay, thanks for your question. Actually, we are going dose the patients with 2 milligram. We know that the drug has a very good safety profile, and interestingly enough and without any connection with the coronavirus, it was a year ago we published our drug can act against the cytokine release syndrome which you have just mentioned is one of the, of course, prominent manifestations of the disease. So we believe that, while we are going to treat patients with moderate Phase 2 study, we will be able to overcome the cytokine release syndrome, which will be expressed in an improvement in the clinical state of the patients.

So, this is approach, and we hope very much that we will be able to prove it. We are expecting the approval or, what we say now, any action from the FDA in the next couple of days, and we will be able to start dosing the patients afterward.

Jason Kolbert

Where exactly are you—you're going to be running this trial in multiple sites in the United States? Will you be running it also in Israel? Are you looking to Europe as well? What kind of costs—how do we calculate this, in terms of our model?

Pnina Fishman, Ph.D.

At this stage, we will be looking at patients in the U.S., we will have couple of centers, and also in Israel. We may later on expand it also to Europe.

Jason Kolbert

Last question is regarding liver cancer. Can you give us some idea of what the timing might be, or what you're thinking internally, in terms of how that trial advances and how is your BD discussions going? It would be great to have a partner that could fund that.

Pnina Fishman, Ph.D.

Yes, sure. Actually we have a protocol for the Phase 3 clinical study, as I have just mentioned, ready to go. Basically, and as of your second question, we have already out-licensed the drug for China and for Korea, and we are now having, as I also mentioned, talks with other companies who would like to in-license this drug, and we hope very much to come up with news very shortly.

Jason Kolbert

Thanks so much for the update, guys.

Pnina Fishman, Ph.D.

You're welcome.

Operator

Once again if you would like to ask a question, please press star, one on your telephone keypad. Once again if you would like to ask a question, please press star, one on your telephone keypad.

Our next question comes from the line of Vernon Bernardino with H.C. Wainwright. Please proceed with your question.

Vernon Bernardino

Hi, Pnina and Motti. Good evening. I know it's really late for you guys. Thanks for having this call.

Pnina Fishman, Ph.D.

Hi.

Vernon Bernardino

So, regarding the planned announced interim analysis for piclidenoson in rheumatoid arthritis and psoriasis, could you remind us again what kind of data to expect?

Pnina Fishman, Ph.D.

Actually, regarding the rheumatoid arthritis study, the patient population are naïve patients, and our aim is at the end of the day to register the drug as first line in patients, and to replace the methotrexate drug which most of the patients will get as the first line. This is as of the rheumatoid arthritis. In the frame of the study, we have a placebo group where we are comparing our drug to—and also a comparator which is methotrexate, and we need to be non-inferior versus methotrexate.

Regarding the psoriasis, it's the same, but we are comparing to Otezla, the Celgene drug. So, we expect that our drug, of course, will win and will be non-inferior, and on Q4 we plan to come with the data, everything is going smoothly regarding the data analysis, so it's coming, it's very soon, and of course we are very positive.

Vernon Bernardino

Perfect. Thanks for reminding us.

I was wondering, regarding the pivotal Phase 3 design for namodenoson in liver cancer, could you provide insights as to the regulators' view, especially with—on discussions fresh from the EMA, into their view of Child-Pugh B7 cirrhotic patients and the effects of namodenoson? Just wonder if you could share some of the insight they provided.

Pnina Fishman, Ph.D.

Sure. The thing is that our drug interestingly was found to be efficacious in a subpopulation which constitutes like 70% of the whole population of patients with advanced liver cancer. This subpopulation is defined as Child-Pugh B, and they do not have any drug currently which they can get.

So, the approach of both agencies was to encourage us to go ahead for this patient population, and this is where we are aiming at. The study is aiming at 500 patients, and there will be an interim analysis like we are doing now with rheumatoid arthritis and psoriasis; we are doing now all the preparatory work, and we will of course let everybody know when we will be ready to embark and initiate the study.

Vernon Bernardino

So, when you mentioned like psoriasis, interim look at half the number of patients? So like 250?

Pnina Fishman, Ph.D.

Correct. Yes. Correct.

Vernon Bernardino

One follow-up now and go back in the queue. Regarding namodenoson and the compassionate use program in Israel, should we expect to see some results or an update on the status of these patients?

Pnina Fishman, Ph.D.

Usually it doesn't go that you give like an overview about these patients, but in general we are treating patients via this program, and there are patients on the drug, which is a very good sign because as we know this is a very advanced patient population. At the time, yes, we will come up and summarize the data with these patients.

Vernon Bernardino

Great. Thank you. I have a few more questions, but I'll get back in the queue. Thank you.

Pnina Fishman, Ph.D.

Okay. Thank you.

Operator

Once again if you would like to ask a question, please press star one on your telephone keypad. Once again if you would like to ask a question, please press star one on your telephone keypad. One moment please as we poll for questions.

We do have a follow-up question for the line of Vernon Bernardino with H.C. Wainwright. Please proceed with your question.

Vernon Bernardino

Hi. Hello again.

Regarding the IND filed for the Phase 2 study with piclidenoson in COVID-19 moderate patients, do you anticipate providing—because you mentioned that one of the things that you've assessed is standard measures of clinical and respiratory status at day 29; but along the way, one of the things that tends to be measured frequently, will you also be collecting perhaps data on the oxygen status of these patients?

Pnina Fishman, Ph.D.

Actually yes, one of the endpoints will be to look if these patients are not anymore on oxygen, need oxygen or not. So, this is additional thing that we will look at, yes.

Vernon Bernardino

Terrific, because, as you probably know by now, that's an early indicator of whether these patients are getting worse or not. Early on in the study, after 28 days of treatment, certainly day 29 would be useful information, but along the way you could gauge as far as how quickly piclidenoson is working. Would you agree?

Pnina Fishman, Ph.D.

Yes, absolutely.

Vernon Bernardino

Okay.

Turning to the assay for cannabis-derived programs, you mentioned it's a biological cell-based in vitro assay; how exactly does the assay work?

Pnina Fishman, Ph.D.

The assay is a cell-based assay. Basically we have different ones. When we want to look at different types of diseases, for example, we have one which can look, of course, at oncological indications, so we can look at different types of cancers in vitro and see if a certain cannabinoid derivative can affect the proliferation or growth or some functional capabilities of a given type of cell. We have different systems for liver cells, which is not related to oncology but to metabolic indications; we have different one for fat cells. So, there are couple of cell-based assay, which we are looking at from a proliferative and from functional point of view. This is how we can segregate and see if a given compound is active or not.

Vernon Bernardino

Terrific. Thank you for providing that additional information. Look forward to continued progress.

Pnina Fishman, Ph.D.

Hey, you are more than welcome.

Operator

As there are no further questions left in the queue, I would like to turn the call back over to Dr. Fishman for any closing remarks.

Pnina Fishman, Ph.D.

Okay, thank you very much, and hope to hear you again in next Q. Bye-bye.

Operator

This concludes today's teleconference, you may now disconnect your lines at this time. Thank you for your participation, and have a wonderful day.

Pnina Fishman, Ph.D.

Thank you.