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GTX INC /DE/  
Form 425  
March 07, 2019

Filings under Rule 425  
under the Securities Act of 1933  
and deemed filed under Rule 14a-12  
of the Securities Exchange Act of 1934, as amended  
Filing by: GTX, Inc.  
Subject Company: GTX, Inc.  
SEC File No.: 000- 50549

In connection with the proposed merger transaction described during this call, GTX, Inc. and Oncternal Therapeutics, Inc. intend to file relevant materials with the Securities and Exchange Commission, or the SEC, including a registration statement on Form S-4 that will contain a prospectus, a proxy statement and an information statement. ***Investors and security holders of GTX and Oncternal are urged to read these materials when they become available because they will contain important information about GTX, Oncternal and the Merger.*** The proxy statement, prospectus, information statement and other relevant materials (when they become available), and any other documents filed by GTX with the SEC, may be obtained free of charge at the SEC web site at [www.sec.gov](http://www.sec.gov). In addition, investors and security holders may obtain free copies of the documents filed with the SEC by GTX by directing a written request to: GTX, Inc., 175 Toyota Plaza, 7th Floor, Memphis, Tennessee 38103, Attention: Corporate Secretary. Investors and security holders are urged to read the proxy statement, prospectus, information statement and other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, 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.

GTX and its directors and executive officers and Oncternal and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of GTX in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the Merger will be included in the proxy statement/ prospectus/information statement referred to above. Additional information regarding the directors and executive officers of GTX is also included in GTX's definitive proxy statement in connection with its 2018 Annual Meeting of Stockholders filed with the SEC on March 23, 2018. These documents are available free of charge at the SEC web site ([www.sec.gov](http://www.sec.gov)) and from the Corporate Secretary of GTX at the address above.

GTX and Oncternal Therapeutics, Inc. Conference Call

March-07-2019

Confirmation #13688553

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Investors and security holders of GTX and Oncternal are urged to read these materials when they become available because they will contain important information about GTX, Oncternal, and the merger. The proxy statement, prospectus, information statement, and other relevant materials, when they become available, and any other documents filed by GTX with the SEC, may be obtained free of charge at the SEC website at [www.sec.gov](http://www.sec.gov).

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Operator: Greetings. Welcome to the GTX and Oncternal Therapeutics, Inc. Conference Call. At this time, all participants are in a listen-only mode. A question and answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press \*0 on your telephone keypad. Please note, this conference is being recorded. I will now turn the conference over to Richard Vincent, Chief Financial Officer, Oncternal Therapeutics, Inc. You may begin.

Richard Vincent: Thank you, operator. I'd like to welcome you to our conference call to discuss the proposed merger between Oncternal Therapeutics, Inc. and GTX, Inc. With me today from GTX is Dr. Robert Wills, Executive Chairman of GTX, and Oncternal's CEO, Dr. James Breitmeyer.

Earlier today, the two companies issued a joint press release announcing the proposed merger. We encourage listeners to review the press release, which is available on the GTX website. This call is also being recorded, and a replay will be available on the investor section of the GTX website for 60 days.

Before beginning the call, I would like to make the following statement regarding forward-looking statements. Certain statements on this conference call regarding the proposed transaction and other contemplated transactions, including statements relating to satisfaction of the conditions and consummation of the proposed transaction, the expected ownership, management and board of directors of the combined company, the alternatives to the proposed transaction, the plans with respect to capitalization of the combined company, and the anticipated timing and effects of the transaction, including as to value creation and growth opportunities, as well as statements regarding Oncernal's plans for following the transaction, including as to its lead compound and future studies, constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are usually identified by the use of words such as anticipates, believes, estimates, expects, intends, may, plans, projects, seeks, should, will, and variations of such words or similar expressions.

GTx intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Security Securities Exchange Act of 1934, as amended, and are making this statement for purposes of complying with these safe harbor provisions. These forward-looking statements reflects GTx's current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to GTx and on assumptions GTx has

made. Although GTX believes that its plans, intentions, expectations, strategies and prospects, as reflected in its forward-looking statements are reasonable, GTX can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond GTX's control.

Actual results might differ materially from those projected in the forward-looking statements due to risks and uncertainties, including those risks and uncertainties listed in the joint press release detailing the proposed transaction, which can be found in the news sections of [www.oncternal.com](http://www.oncternal.com) and [www.gtxinc.com](http://www.gtxinc.com) and as an exhibit to the Form 8-K GTX filed this morning, which is available on [www.gtxinc.com](http://www.gtxinc.com) and [www.sec.gov](http://www.sec.gov). And those risks and uncertainties detailed in the risk factors section of GTX's Form 10-K and Forms 10-Q filed with the SEC, as well as other filings GTX makes with the SEC from time to time. Many of these factors will determine actual results beyond GTX's, Oncternal's, or the combined company's ability to control or predict.

GTX disclaims any obligation to update information contained in these-forward looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Please note that we will also have a brief Q&A at the end of this call. With that, I'll now turn the call over to GTX's Executive Chairman, Rob Wills.

Robert Wills: Thank you, and good morning, everyone. I am pleased to share with you the news today about our planned merger with Oncernal Therapeutics, which will create an exciting NASDAQ listed clinical stage company developing a diverse pipeline of novel therapies for cancers with critical unmet medical need.

Since last fall, our management team and board have conducted a thorough review and assessment of our business objectives and have undertaken a comprehensive process to explore strategic alternatives to deliver both near and long-term value for GTX shareholders. As previously stated, we have been focused on advancing our novel selective androgen receptor degrader, or SARD, technology as a potential first-in-class treatment of castrate-resistant prostate cancer.

We also have been exploring ways to realize value from our selective androgen receptor modulator, or SARM, assets. We believe the proposed merger with Oncernal provides a strong path forward for both companies. The combined company will represent several key characteristics found in successful biotech companies. One, a diverse clinical stage pipeline of assets with near term value inflection points; two, several novel preclinical programs, which

includes the GTX SARD program. Three, a management team with expertise in developing oncology clinical and preclinical assets; and four, sufficient capital to advance these programs. Oncternal's President and CEO, Dr. Jim Breitmeyer, will now provide background on Oncternal and its promising pipeline, and recent clinical progress.

James Breitmeyer: Thank you, Rob. It's a pleasure to be here today to discuss the planned merger and the exciting oncology company that it will create. First, I'd like to say that it has been a delight to work with GTX and its leadership over the past few months. The entire team has been mission-oriented and fully focused on creating long term value for shareholders. We are excited to move ahead together, and I'd like to share with you more about our mission, our pipeline programs, and the opportunity to create needed new therapies for the treatment of cancer. Perhaps that will shed some light on what attracted the GTX team to Oncternal during their strategic review process.

Oncternal Therapeutics is a clinical-stage oncology company developing a diverse pipeline of potential treatments for cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer genesis and progression. The pipeline includes multiple key programs. Cirmtuzumab is an investigational monoclonal antibody that is designed to inhibit the ROR1 receptor and is in Phase 1/2 development for several hematologic cancers. TK-216, an investigational small molecule that is



designed to inhibit ETS-family oncoproteins, is in Phase 1 development as a potential treatment for Ewing's sarcoma, a rare pediatric cancer. We are also developing a CAR-T therapy targeting ROR1, which is currently in preclinical development as a potential treatment for solid tumors and hematologic cancers.

We are headquartered in San Diego, where we've built an experienced leadership team. Through multiple financing rounds as a private company, we've succeeded in attracting investors that are committed to advancing our pipeline rapidly and efficiently, and to bringing patients a new wave of first-in-class cancer treatments.

With that overview, I'd like to give you a more detailed look at the science behind Oncternal and our portfolio. Each of our product candidates is designed to attack very specific mechanisms that cancer cells use to grow, thrive or metastasize. Our scientific approach focuses on attacking those pathways, which are not expressed in most healthy cells, in order to inhibit cancer cell growth, while working to maximize tolerability for the patient. With our drug development expertise and a strong network of academic collaborations, we are uniquely positioned to turn those important research discoveries into new potential therapies for patients with cancers with critical unmet medical need.

Now, let's turn back to our pipeline. Oncernal's lead program, cirmtuzumab, is an investigational, potential first-in-class anti-ROR1 monoclonal antibody, that is currently in a Phase 1/2 study as a potential treatment for various B-cell malignancies, including chronic lymphocytic leukemia, or CLL, and mantle cell lymphoma, or MCL. We are evaluating cirmtuzumab in combination with ibrutinib, which is currently marketed as IMBRUVICA.

While early, we have already seen clinical responses suggesting that cirmtuzumab may synergize with ibrutinib, and we are expecting data from the Phase 1 and 2a portions of this study later this calendar year. Additionally, a separate investigator-initiated Phase 1 study of cirmtuzumab, in combination with paclitaxel for women with metastatic breast cancer, is open and enrolling patients at the University of California in San Diego, or UC San Diego.

Cirmtuzumab was developed at UC San Diego based on the pioneering scientific research of Thomas Kipps, MD, PhD, and his colleagues at the Moores Cancer Center. Oncernal holds an exclusive worldwide license to develop and commercialize therapeutic antibody candidates, including cirmtuzumab and CAR-T recognizing ROR1. The development of cirmtuzumab has also been supported by more than 35 million in grant funding from the California Institute for Regenerative Medicine, or CIRM.

There is tremendous unmet medical need for patients with both CLL and MCL, because they can cause disabling constitutional symptoms including lymph node, spleen, and liver enlargement, along with bone marrow infiltration, causing marrow failure, immune deficiency, and ultimately significant morbidity and early mortality.

Ibrutinib is becoming a standard of care in the modern treatment of CLL and MCL. However, most patients treated with ibrutinib alone achieve only a partial response and, therefore, an agent that works synergistically with ibrutinib to increase the number of patients achieving a complete response is needed. Early clinical data suggest that cirmtuzumab may synergize with ibrutinib, and we are evaluating this combination as a potential treatment for both CLL and MCL.

We are very encouraged by the early responses observed in the Phase 1/2 combination trial of cirmtuzumab with ibrutinib. We look forward to additional response data and initiation of the randomized Phase 2 portion of the clinical trial later this year, as well as the continued progress of the ongoing Phase 1 breast cancer study underway with UC San Diego, which we believe supports the further development of cirmtuzumab in additional indications.

Our next clinical program is TK216, an investigational, potential first-in-class small molecule designed to inhibit the biological activity of ETS-family transcription factor oncoproteins in a

variety of tumor types. We plan to evaluate TK216 alone and in combination with vincristine in a Phase 1 study in patients with relapsed or refractory Ewing's sarcoma. There is tremendous need for new, targeted therapies for this devastating disease of children. And the hope is that if TK216 is successfully developed, we can seek approval through an expedited approval pathway.

Ewing's sarcoma is the second most common pediatric bone tumor. In Ewing's sarcoma, TK216 is designed to target the well-characterized fusion proteins that cause the disease. Our Phase 1 trial of TK216 is ongoing, and we are closing in on a recommended dosing regimen. Oncternal is also planning clinical studies of TK216 for other cancers whose cells carry mutant or overexpressed levels of ETS-family oncogenes, such as acute myeloid leukemia, and eventually, prostate cancer.

Our third program is an investigational ROR-1 targeted CAR-T therapy, which is currently in preclinical development with our partner UC San Diego for hematologic and solid tumors, with funding from CIRM. CAR-T therapies are T cells that have been engineered to target and engage a specific marker on cancer cells in an effort to direct an immune response against those cancer cells. Remarkable clinical responses with CAR-T therapies have been observed in leukemias, lymphomas and myeloma, but some of these treatments have been associated with considerable toxicity, including cytokine release syndrome and neurologic toxicity, each of which can be severe and sometimes fatal.

We believe ROR1 is an attractive target for a CAR-T therapy for multiple reasons. First, ROR1 is expressed on the tumors of a majority of patients across a wide variety of common cancers, making a ROR1 CAR-T potentially applicable across multiple indications. The same ROR1 CAR-T system could be tested in hematological cancers and then applied to solid tumors. Second, our ROR1 targeting antibodies are designed not to recognize normal adult tissues, which we believe may lead to improved tolerability. Third, the ROR1 on the tumor cell confers a fitness and survival advantage. So, eliminating these cells may remove the most aggressive cells within the tumor.

Another potential advantage is that it may be difficult for a cancer cell to lose its ROR1 expression without also losing some of its survival or fitness advantage, making antigen negative relapses more unlikely. We are hoping to be in or near clinical trials with our CAR-T therapeutic candidate in the next year.

Oncternal is also very enthusiastic about the addition of GTx's SARD program to Oncternal's pipeline. As GTx shareholders are well aware, the GTx SARDs in development are potential first-in-class oral therapies designed to treat castration-resistant prostate cancer in men who have failed or are not responsive to current androgen targeted therapies. The lead compounds have shown activity against enzalutamide resistant prostate cancers in a rodent xenograft model.

Adding our expertise in prostate cancer to GTX's excellent initial work, we will continue to develop these compounds with the goal of progressing a lead SARD candidate to an IND filing.

As you can see, I am excited about the potential of our merged pipeline and by the future of the combination of Oncternal and GTX. Our team has identified a number of high value product candidates that we are rigorously testing in clinical and preclinical development. We have clear development paths for these programs and key value-driving inflection points in the year ahead. I look forward to sharing more about our strategy and our progress with shareholders in the months to come.

I will now turn the call over to Richard Vincent, CFO of Oncternal, to describe the transaction.

Richard Vincent: Thank you, Jim. The merger is structured as a stock-for-stock transaction whereby all of Oncternal's outstanding shares of common stock and securities convertible into or exercisable for Oncternal's common stock will be converted into GTX common stock and securities convertible into or exercisable for GTX common stock. Immediately following the closing of the transaction, the former stockholders of Oncternal will hold approximately 75 percent of the outstanding shares of common stock of the combined company.

GTX stockholders of record, as of immediately prior to the effective time of the merger, will retain an ownership interest representing approximately 25 percent of the outstanding shares of common stock of the combined company and will also receive a non-transferable contingent value rights, or CVRs, entitling them to receive 50 percent of any net proceeds derived from the grant, sale or transfer of rights to SARD or SARM technology during the term of the CVRs and to receive royalties on the sale any SARD or SARM products by the combined company during the term of the CVRs.

Under certain circumstances further described in the merger agreement, the exchange ratio of the outstanding shares of common stock of the combined company may be adjusted upward or downward based on cash levels of each of the companies at closing.

Upon closing of the transaction, GTX will be renamed Oncternal Therapeutics, Inc. and will be headquartered in San Diego, California under the leadership of Oncternal's current management team. Oncternal's current CEO, Jim Breitmeyer, will serve as president and CEO of the combined company. David Hale, cofounder of Oncternal and a 35-year veteran of numerous successful private and public biotech companies, will become chairman of the board of the combined company. The board of directors of the combined company will be comprised of nine members, including seven Oncternal designated board members, and two members from the GTX board, Dr. Robert Wills and Dr. Michael Carter.

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The combined company is expected to trade on The NASDAQ Capital Market under a new ticker symbol, ONCT. The merger agreement has been unanimously approved by the board of directors of each company. The transaction is expected to close in the second quarter of 2019, subject to approvals by stockholders of each company and other customary closing conditions.

The GTX and Oncernal management teams and the company's respective board of directors truly believe this proposed merger will provide the best opportunity to our respective shareholders for future value creation.

Over the last few months, we've come to know the GTX management team well and have tremendous respect for the organization they have built. We believe by combining GTX's technologies with our own pipeline programs in oncology, including the potential we have seen recently from the early clinical successes of our lead program, cirmtuzumab, we have the opportunity to build real value for the shareholders of both GTX and Oncernal in the years to come. We are excited about this opportunity and look forward to updating you on our progress periodically following the closing of this merger.

With that, let's open the call for questions. Operator?



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Operator: Thank you. At this time, we will be conducting a question and answer session. If you'd like to ask a question, please press \*1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press \*2 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 keys. One moment, please, while we poll for questions.

Thank you. Our first question comes from the line of Mike Ulz with Robert W. Baird. Please proceed with your question.

Mike Ulz: Yeah. Hi, guys. Thanks for taking the question. Maybe just one for Rob to start with. Just with respect to the SARD program, maybe you can comment on your current thinking there. I think in the past, you were potentially considering partnering it versus continuing development in-house. Maybe you can just comment on the current thinking with respect to that.

Robert Wills: Mike, first, thanks for calling in.

I think what we would like to see first now that we're becoming a new company is let the Oncernal management get their hands and arms around the program to best decide the next steps. As you know, we didn't have the preclinical infrastructure at GTX to be able to take this forward. We could have, but it would've been more of a challenge. We would've had to contract everything out.

In this case, we're coming into an organization where they have that infrastructure and they have the oncology expertise. So, at this point you know, we're never opposed or I can't speak for the new company, but we're generally never opposed to seeking out external partnerships and developing and commercializing programs. But, I would think in the near future, the intent would be for Oncernal Therapeutics to take this forward to IND capability and then go from there.

Mike Oltz: Got you. That's helpful. And then maybe just one more question from me. Just with respect to cirmtuzumab, you mentioned providing some data later this year. Just curious if you can maybe be a little bit more specific in terms of the timing. And then maybe give us a sense of what types of data to expect. Will it be more a safety-focused data release or will we see some efficacy as well?

James Breitmeyer: Thank you for the question, Mike. We will have efficacy data to talk about this year. The treatment of patients with CLL, with the combination of cirtuzumab and ibrutinib, is enrolling particularly well. We've completed our initial dose finding portion of the study and are enrolling in an expansion cohort now. And we would expect to have patients treated of sufficient duration to be able to discuss both efficacy and safety outcomes this year. We are anticipating reporting some of those data at a major oncology meeting sometime this year as well.

We are also doing an initial study in breast cancer using cirtuzumab and paclitaxel based on some strong preclinical evidence of synergy between those agents. And we would expect to have the safety data from that study ready to discuss this year as well. And it's a single arm study, but there may be some early indications of efficacy to discuss from that one as well.

Mike Ulz: Got it. Thank you.

Operator: Thank you. Ladies and gentlemen, as a reminder, if you'd like to join the question queue, please press \*1 at this time.

Our next question comes from the line of Adam Walsh with Stifel. Please proceed with your question.

Adam Walsh: Good morning. Congrats on this proposed merger. I just have a couple of quick questions. The first is since part of the value for the GTX shareholders rests on the CVR rights to the SARD program, can you elaborate a little bit on what the term of the CVR rights are? And it mentions in the press release that holders of the CVRs could receive royalties on the sale of any SARD products by the combined company under that term. What kind of royalties? Just trying to get the GTX shareholders a little better sense of what the value of that CVR looks like. Thanks.

Richard Vincent: Thanks for the question, Adam. The CVR portion of the deal, there are two elements to it. One is in the event that the program is advanced pre-clinically here and then partnered out to the extent that there are proceeds that come out of a future sale of the program, the net proceeds of that transaction would be split 50/50 between the CVR holders as well as the post-merger combined company.

In the event that the products are retained and advanced and commercialized within Onceternal Therapeutics post-merger, then there would be a high single digit royalty that would be paid

out to the CVR holders. And there is a right of offset of half of the development cost against the future royalties until there's a 50/50 split of all development costs through commercialization.

Adam Walsh: Excellent. That's helpful. And then just a couple oh, go ahead.

Richard Vincent: The initial term of the CVR is 10 years, with a potential tail for five years, depending on when a deal may be struck. And the royalties would last if we commercialize on our own, the royalty stream would last for the duration of 15 year period of time from the closing of the transaction.

Adam Walsh: That's perfect. Thank you. And then a couple of others, if I could. Just to follow up on the cirmtuzumab Phase 1/2 data, I don't want to put you guys on the spot, but what kind of efficacy outcomes will you be looking at? You know, what metrics should we be looking for exactly? And of those metrics, can you just contextualize, any kind of expectations? How would we know success if it happens?

And then a final one, just on the TK-216, will we see the Phase 1 data there? And expect you to start either Phase 2 or pivotals? Thanks.

James Breitmeyer: Thank you, Adam. So, the unmet medical need for patients who are taking single agent ibrutinib is that they get good partial responses, CLL in particular, but this is also true for mantle cell lymphoma. But, complete responses are not common. And so, the endpoint that we're looking for is complete responses. And that's a very well characterized endpoint and straightforward to evaluate. So, we will be talking about, we hope, a complete response rate that we hope is substantially higher than the approximately 7 percent rate of achieving a complete response that is typical for CLL patients who are treated with ibrutinib and have been treated with other prior therapies.

So, for TK-216, the Phase 1 portion of our Ewing's sarcoma program, we do expect to be reporting the data from that Phase 1 study, both safety and efficacy, by early 2020. It's a little hard to project the timing because Ewing's sarcoma is an uncommon pediatric tumor. But, we are forecasting to be able to discuss both Phase 1 dose escalation and expansion cohort data over the course of the next year and ideally during 2019.

Adam Walsh: Excellent. Thank you very much.

James Breitmeyer: Thanks, Adam. You're welcome. Thank you.

Operator: Thank you. Ladies and gentlemen, as a reminder, again, if you'd like to join the question queue, please press \*1 at this time. We'll pause a moment to allow for any other questions.

Thank you. At this time, we reached the end of our question and answer session. I'll now turn the floor back over to Dr. Robert Wills for any closing comments.

Robert Wills: In closing, I'd just like to reiterate that I believe the future of this combined organization is bright, and I look forward to being a part of its growth as a board member. Oncernal has assembled a number of promising cancer drug candidates and has the right team for the job. With their oncology focus and disease specific expertise, they also have the means to move the SARD program forward in castrate-resistant prostate cancer.

We believe that this merger will provide immediate and long-term value to shareholders, and we look forward to updating you on our progress in the future.

Operator: Thank you. Ladies and gentlemen, this concludes today's conference. You may disconnect your lines at this time. Thank you for your participation, and have a wonderful day.