

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

CURRENT REPORT

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

Date of report (Date of earliest event reported) **November 10, 2014**

GTx, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50549
(Commission File
Number)

62-1715807
(IRS Employer Identification No.)

175 Toyota Plaza
7th Floor
Memphis, Tennessee
(Address of Principal Executive Offices)

38103
(Zip Code)

Registrant's telephone number, including area code: **(901) 523-9700**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.02 Results of Operations and Financial Condition.

On November 10, 2014, GTx, Inc. issued its financial press release for the third quarter ended September 30, 2014, a copy of which is furnished as Exhibit 99.1 to this Current Report.

This release is furnished by GTx pursuant to Item 2.02 of Form 8-K and is not to be considered "filed" under the Exchange Act, and shall not be incorporated by reference into any previous or future filing by the Registrant under the Securities Act or the Exchange Act.

ITEM 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

**Exhibit
Number**
99.1

Description
Press Release issued by GTx, Inc. dated November 10, 2014

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 10, 2014

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

GTx PROVIDES CORPORATE UPDATE AND REPORTS THIRD QUARTER 2014 FINANCIAL RESULTS

- Company's primary corporate focus targets the androgen receptor in women with advanced breast cancer -

- Closing of recently announced private placement will provide cash through 2016 and key breast cancer milestones -

- Conference call today at 9:00 a.m. ET -

MEMPHIS, TN. — November 10, 2014 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the third quarter ended September 30, 2014 and highlighted recent accomplishments and upcoming milestones. In addition, management outlined its refocused development strategy to target the androgen receptor in women with advanced breast cancer using enobosarm, the Company's oral nonsteroidal selective androgen receptor modulator. The Company also highlighted clinical progress with GTx-758, its oral nonsteroidal selective estrogen receptor alpha agonist, being studied for secondary hormonal therapy in men with castration resistant prostate cancer.

In a separate release issued this morning, the Company announced that it has entered into a definitive purchase agreement providing for the private placement of its securities. The aggregate purchase price of the private placement, subject to the satisfaction of customary closing conditions, is \$43.4 million, which is expected to result in approximately \$42.8 million of net proceeds. Additional details regarding the private placement will be included in a current report of the Company on Form 8-K, to be filed with the SEC.

"With breast cancer now as our primary focus and the inclusion of a new, well-respected investor group, Biotechnology Value Fund, L.P. and other affiliates of BVF Partners L.P., in our recently announced financing, we have the momentum and will have the resources to move our clinical development activities to the next set of important company milestones," said Marc S. Hanover, interim CEO, President and COO of GTx. "Given the preclinical and clinical results we have developed to date, we believe there is a strong rationale to target the androgen receptor in women with metastatic breast cancer whose tumors express ER and AR, and women with advanced AR positive triple negative breast cancer."

Recent Highlights and Upcoming Activities

Enobosarm is the Company's lead product candidate and is being developed for the targeted treatment of estrogen receptor (ER) positive and androgen receptor (AR) positive breast cancer, as well as AR positive triple negative breast cancer: Positive results from an ongoing Phase 2 trial of enobosarm 9 mg for the treatment of patients with ER positive and AR positive metastatic breast cancer have demonstrated clinical benefit at six months and have exceeded the pre-defined statistical threshold requiring that at least 3 of 14 patients with an AR positive metastatic tumor demonstrate clinical benefit.

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- Updated results from this trial have been accepted as a poster presentation at the San Antonio Breast Cancer Symposium on December 10, 2014, in San Antonio, Texas. The results will be presented by the principal clinical investigator for this ongoing enobosarm Phase 2 trial, Dr. Beth A. Overmoyer, M.D., director of the Inflammatory Breast Cancer Program at the Susan F. Smith Center for Women's Cancers at Dana Farber Cancer Institute, and assistant professor of Medicine at Harvard Medical School.
- The Company plans to commence, in the first half of 2015, two additional open-label Phase 2 clinical trials of enobosarm; one in patients with ER positive and AR positive metastatic breast cancer and another in patients with advanced AR positive triple negative breast cancer. The Company anticipates clinical data from the first stage of each of these Phase 2 clinical trials in the second half of 2016.

Enobosarm 3 mg is being evaluated for the potential prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (NSCLC): The Company recently met with the Medicines and Healthcare Products Regulatory Agency (MHRA) and believes, based on input from the MHRA, that data from the POWER trials may not be sufficient to support the filing and approval of a MAA in the European Union for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC, without confirmatory data for physical function from another Phase 3 clinical trial for this indication. The Company currently does not intend to file a MAA and will evaluate whether there is commercial rationale and partner interest to support additional clinical development required for approval.

GTx-758 (Capesaris®) is being studied for secondary hormonal therapy in men with castration resistant prostate cancer and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with ADT: GTx continues to enroll patients in an open-label, Phase 2 clinical study of GTx-758 to treat men with metastatic and non-metastatic castration resistant prostate cancer (CRPC) and is evaluating the safety and efficacy of two doses (125 mg and 250 mg) of GTx-758.

- The Company has completed enrollment of the 125 mg arm and expects to complete enrollment in the 250 mg arm by the end of 2014.
- Once top-line results are available, which the Company expects early in the second quarter of 2015, the Company will evaluate potential next steps in the clinical development of GTx-758, including potentially seeking a partnering or collaboration agreement in order to fund additional clinical development.

Third Quarter and Nine Months 2014 Financial Results

- As of September 30, 2014, cash and short-term investments were \$11.5 million compared to \$14.7 million at December 31, 2013. Reported third quarter cash and short-term investments does not include the approximately \$42.8 million in net proceeds the Company will receive upon closing of the private placement announced today.
- Research and development expenses for the quarter ended September 30, 2014 were \$3.4 million compared to \$6.5 million for the same period of 2013.

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- General and administrative expenses for the quarter ended September 30, 2014 were \$1.6 million compared to \$2.5 million for the same period of 2013.
- The net loss for the quarter ended September 30, 2014 was \$4.9 million compared to a net loss of \$8.9 million for the same period in 2013. The net loss for the nine months ended September 30, 2014 was \$24.9 million compared to a net loss of \$34.3 million for the same period in 2013.
- GTx had approximately 76.0 million shares outstanding as of September 30, 2014, and upon closing of the private placement announced today, the Company expects to have approximately 140.3 million shares outstanding.

About enobosarm (GTx-024) to treat breast cancer

Enobosarm, an oral nonsteroidal selective androgen receptor modulator, is being studied for the targeted treatment of estrogen receptor positive and androgen receptor positive metastatic breast cancer. Prior clinical studies have shown that women with metastatic breast cancer who have been previously treated with tamoxifen and whose cancer has progressed have responded to treatment with steroidal androgens, with overall response rates ranging from 20 to 60 percent. Because steroidal androgens have unwanted virilizing side effects, they have limited widespread clinical use. GTx believes that a selective androgen receptor modulator, like enobosarm, by targeting the androgen receptor in metastatic breast cancer, has the potential to provide clinical benefit to women with advanced breast cancer while minimizing these unwanted side-effects associated with steroidal androgens. In addition, the Company plans to evaluate enobosarm in AR positive triple negative breast cancer. For more information about enobosarm, please visit www.gtxinc.com

About enobosarm (GTx-024) to prevent and treat muscle wasting in NSCLC

Enobosarm, an oral nonsteroidal selective androgen receptor modulator, is being developed for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Enobosarm 3 mg, which has been evaluated in two Phase 3 clinical trials, POWER1 (platinum plus taxane chemotherapy) and POWER2 (platinum plus non-taxane chemotherapy), failed to achieve the statistical significance required by the Food and Drug Administration (FDA) for marketing approval in the US. GTx has met with regulators in both the US and Europe and is evaluating whether there is commercial rationale and partner interest to support additional clinical development required for approval. For more information about enobosarm, please visit www.gtxinc.com

About GTx-758 (Capesaris®) to treat men with castration resistant prostate cancer

GTx-758, an oral nonsteroidal selective estrogen receptor alpha agonist, is being studied for secondary hormonal therapy in men with castration resistant prostate cancer (CRPC) and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with androgen deprivation treatment (ADT). GTx is enrolling an open-label, Phase 2 clinical study of GTx-758 to treat men with metastatic and non-metastatic CRPC. Data from the study is expected early in the second quarter of 2015. For more information about GTx-758, please visit www.gtxinc.com

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Conference call and Webcast

There will be a conference call today at 9:00 a.m. Eastern Time. To listen to the conference call, please dial 877-415-3184 from the United States or Canada or 857-244-7327 from other international locations. The access code for the call is 54016257. A playback of the call will be available from approximately 1:00 p.m. Eastern Time today through November 24, 2014 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from other international locations and referencing reservation number 43674900. Additionally, you may access the live and subsequently archived webcast of the conference call from the Investor Relations section of the Company's website at <http://www.gtxinc.com>.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules for the treatment of cancer, including treatments for breast and prostate cancer, cancer supportive care, including prevention and treatment of cancer-related muscle wasting, and other serious medical conditions.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements relating to GTx's planned clinical trials for enobosarm (GTx-024) and its ongoing clinical trial of GTx-758 (Capesaris®), including the anticipated timing of initiation, enrollment in and expected data from such trials, statements related to the potential to undertake additional development of enobosarm 3 mg and GTx-758 and GTx's plans or possible plans related thereto, and statements relating to the anticipated closing of, and the amount of anticipated proceeds from, GTx's recently announced private placement of its securities. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risks (i) that clinical trials being conducted or planned to be conducted by GTx may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated, including as a result of GTx's failure to consummate the recently announced private placement; (ii) that the initiation and conduct of GTx's two planned Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer are wholly contingent on the Company completing the recently announced private placement on the anticipated terms; (iii) that GTx may be unable to satisfy the conditions to the closing of the private placement and may be unable to consummate the private placement on the anticipated terms or at all, which would severely harm the Company's ability to execute on its stated strategy; (iv) that any additional clinical development of GTx's product candidates beyond the two planned Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer is contingent on GTx entering into new collaborative arrangements with third parties for such development or otherwise obtaining sufficient additional capital to permit such development, which it may be unable to do; or (v) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all. In addition regardless of whether the private placement is ultimately consummated, GTx will continue to need additional funding and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product candidate development programs and potentially cease

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operations. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's quarterly report on Form 10-Q for the quarter ended June 30, 2014 and its future reports, including the Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, contain under the heading, "Risk Factors" a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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Source: GTx, Inc.

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GTx, Inc. Condensed Balance Sheets (in thousands, except share data)

| | September 30, 2014 (unaudited) | December 31, 2013 |
|--|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 9,627 | \$ 14,529 |
| Short-term investments | 1,915 | 200 |
| Prepaid expenses and other current assets | 919 | 442 |
| Total current assets | 12,461 | 15,171 |
| Property and equipment, net | 42 | 112 |
| Intangible and other assets, net | 513 | 322 |
| Total assets | <u>\$ 13,016</u> | <u>\$ 15,605</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 179 | \$ 808 |
| Accrued expenses and other current liabilities | 2,139 | 3,759 |
| Total current liabilities | 2,318 | 4,567 |
| Other long-term liabilities | 82 | 354 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value: 200,000,000 and 120,000,000 shares authorized at both September 30, 2014 and December 31, 2013, respectively; 76,014,531 and 63,185,389 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively | 76 | 63 |
| Additional paid-in capital | 490,766 | 465,981 |
| Accumulated deficit | (480,226) | (455,360) |
| Total stockholders' equity | 10,616 | 10,684 |
| Total liabilities and stockholders' equity | <u>\$ 13,016</u> | <u>\$ 15,605</u> |

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GTx, Inc. Condensed Statements of Operations (in thousands, except share and per share data) (unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--------------------------------------|-------------------------------------|-------------------|------------------------------------|--------------------|
| | 2014 | 2013 | 2014 | 2013 |
| Expenses: | | | | |
| Research and development expenses | \$ 3,362 | \$ 6,477 | \$ 17,616 | \$ 26,230 |
| General and administrative expenses | 1,594 | 2,483 | 7,275 | 8,190 |
| Total expenses | 4,956 | 8,960 | 24,891 | 34,420 |
| Loss from operations | (4,956) | (8,960) | (24,891) | (34,420) |
| Other income, net | 21 | 23 | 25 | 99 |
| Net loss | <u>\$ (4,935)</u> | <u>\$ (8,937)</u> | <u>\$ (24,866)</u> | <u>\$ (34,321)</u> |
| Net loss per share: | | | | |
| Basic and diluted | <u>\$ (0.06)</u> | <u>\$ (0.14)</u> | <u>\$ (0.34)</u> | <u>\$ (0.54)</u> |
| Weighted average shares outstanding: | | | | |

