UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): January 8, 2024

G1 THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-38096	26-3648180
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

700 Park Offices Drive Suite 200 Research Triangle Park, NC	27709
(Address of principal executive offices)	(zip code)

Registrant's telephone number, including area code: (919) 213-9835

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

☐ Written communications pursuant to Rule 425 under the Securities Act (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))

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, $0.0001 par value	**GTHX**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

As of December 31, 2023, G1 Therapeutics, Inc.'s cash, cash equivalents and investments balance was approximately $82 million.

Item 7.01 Regulation FD Disclosure.

Attached to this Current Report on Form 8-K as Exhibit 99.1 is a presentation (the "Presentation"), which is incorporated herein by reference. The Company will use the Presentation in various meetings with securities analysts, investors, and others beginning January 8, 2024.

Pursuant to General Instruction B.2 of Current Report on Form 8-K, the information contained in, or incorporated into, Item 7.01, including the Presentation attached hereto as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation dated January 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

G1 THERAPEUTICS, INC.

By: */s/ Monica Roberts Thomas*
Monica Roberts Thomas
General Counsel

Date: January 8, 2024


G1
THERAPEUTICS
42nd Annual J.P. Morgan Healthcare Conference
Wednesday January 10, 1:30 PM PT
Developing and Delivering Next Generation Therapies that Improve the Lives of People Living with Cancer

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "could," "believe," "goal," "projections," "indicate," "potential," "opportunity," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this presentation include, but are not limited to, those relating to expectations for the commercial success of COSELA® (trilaciclib), our ability to further develop and expand the use of COSELA in the treatment of extensive-stage small cell lung cancer, the therapeutic potential of trilaciclib in the treatment triple-negative breast cancer and with ADCs, that trilaciclib's greatest effect is on longer term endpoints including OS, that trilaciclib may improve long-term immune surveillance for additional benefit after treatment, the expectation that achievement of the OS endpoint in the ongoing PRESERVE 2 Phase 3 clinical trial is expected to enable global regulatory submissions in 2024 and beyond, that G1's cash runway is expected to extend into 2025, that impact from platinum based chemotherapy shortages have begun to abate, global expansion, and that achieving the OS primary endpoint in the Phase 3 TNBC trial may serve as a catalyst for global expansion plans. In addition, COSELA may not achieve the degree of market acceptance for commercial success, the potential to demonstrate trilaciclib + gem/carbo as 1L TNBC standard of care, and the impact of pandemics such as COVID-19 (coronavirus), are based on our expectations and assumptions as of the date of this presentation. Each of these forward-looking statements involves risks and uncertainties that may cause our actual results to materially differ from those expressed or implied in such statements. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. Applicable risks and uncertainties are discussed in our filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, our ability to successfully commercialize COSELA; the dependence on the commercial success of COSELA; our ability to complete clinical trials for, obtain approvals for, and commercialize additional indications of COSELA and any of our product candidates other than COSELA; our initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a commercial-stage company; chemotherapy shortages and market conditions. Except as required by law, we assume no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

G1 Therapeutics: Opportunities for Significant Growth

Unique Marketed Product in U.S. with Growing Revenue	• Novel product that provides meaningful patient benefits via transient G1 arrest of HSPC's and T-Cells • Established U.S. commercial infrastructure with growing revenue in initial ES-SCLC indication
Potential to Transform 1L TNBC Treatment	• Phase 3 readout provides important potential near-term global commercial opportunity (interim analysis in 1Q) • Robust OS observed in randomized Phase 2 with improvement continuing with subsequent therapies
Opportunity to Improve Safety and Efficacy of Leading ADCs	• Phase 2 with sacituzumab govitecan serves as proof-of-concept for trilaciclib in TROP2 ADC combinations • Observing robust safety and tolerability improvements with potential survival benefit
Positioned for Global Expansion and Future Growth	• Evaluating additional late-stage studies and conducting research into next generation products • Planning to secure a partner for global expansion following a successful 1L TNBC readout • Anticipated cash runway into 2025

Note: HSPC's: Hematopoietic stem and progenitor cells, ES-SCLC: Extensive Stage Small Cell Lung Cancer, TNBC: Triple negative breast cancer; ADC" antibody-drug conjugate

Agenda

Unique Marketed Product in U.S. with Growing Revenue

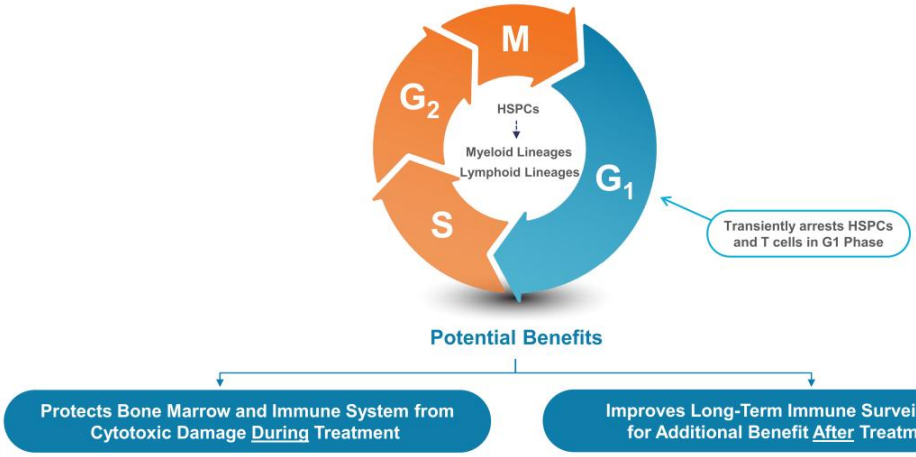
Potential to Transform 1L TNBC Treatment

Opportunity to Improve Safety and Efficacy of Leading ADCs

Positioned for Global Expansion and Future Growth

Trilaciclib Mechanism of Action

Temporarily Blocks Progression through Cell Cycle Via Transient CDK4/6 Inhibition

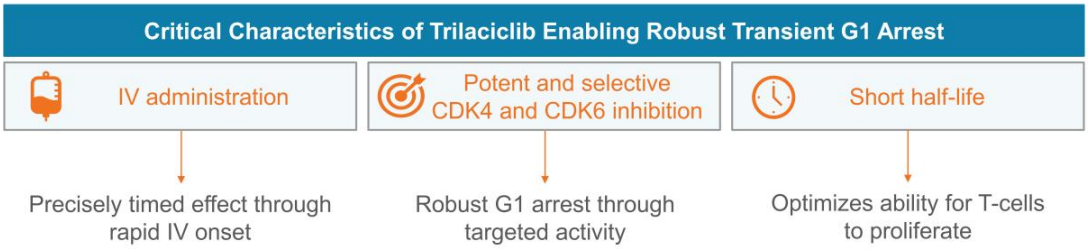


Potential Benefits

- **Protects Bone Marrow and Immune System from Cytotoxic Damage During Treatment**
- **Improves Long-Term Immune Surveillance for Additional Benefit After Treatment**

G1 THERAPEUTICS

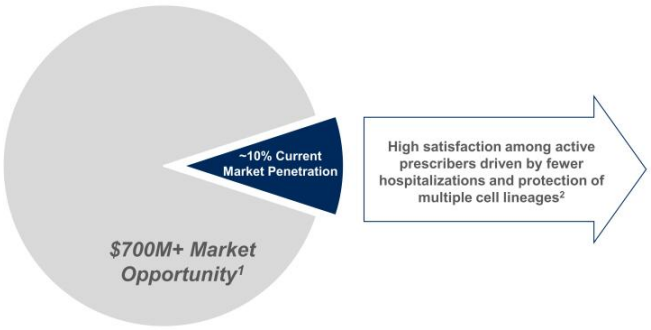
Unique Product Attributes for Robust Transient G1 Arrest



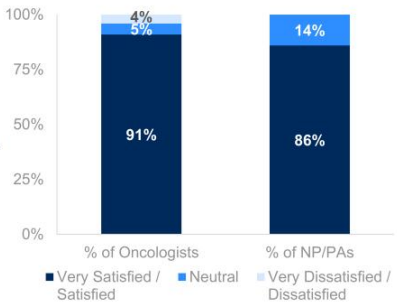
These attributes are critical to maximize the benefits of transient CDK4/6 inhibition

Potential for Strong Growth within U.S. ES-SCLC Market

~20K ES-SCLC Patients in U.S. Receive Indicated Chemotherapy



Satisfaction with COSELA® (trilaciclib)[3]

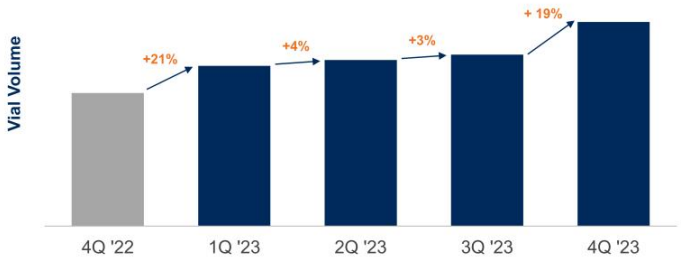


Meaningful opportunity to continue growing share in $700M+ U.S. ES-SCLC market, with high levels of satisfaction expressed by existing prescribers

1. Based on ~20k patients and $36,600 current WAC pricing for 24 vials of trilaciclib (assumed 4 cycles per patient based on standard 1L ES-SCLC chemotherapy regimens)
2. According to active prescriber data from internal ATU Tracking Studies, Q3 2023, which is further supported by Real World Evidence
3. Prescriber data from internal ATU Tracking Studies, Q3 2023

COSELA U.S. Growth Regained Momentum in 4Q23

2023 Quarterly COSELA Vial Volume and Growth in U.S.



- **Platinum chemotherapy shortage hindered 2Q and 3Q growth**
  - Combination with platinum chemotherapy comprises large portion of COSELA use (~90%)
- **Impact from platinum-based chemotherapy shortages has begun to abate in 4Q**
  - 19% increase in volume over 3Q23
  - >50% increase in volume over 4Q22

COSELA vial volume regained meaningful growth in fourth quarter of 2023 upon easing of platinum chemotherapy shortages

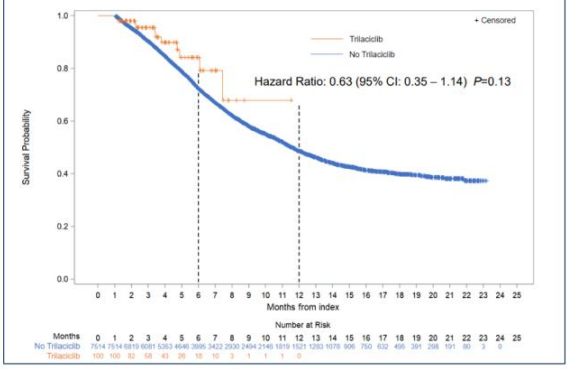
Note: Growth figures above represent sequential quarterly growth

Potential for Future Development and Expansion in ES-SCLC

Expected Future Data in ES-SCLC

	Lurbinectedin Combination (Phase 2)	Topotecan Combination Post-Marketing Study	Real World Evidence
Setting	2L ES-SCLC	2L ES-SCLC	1L/2L ES-SCLC
Combination	Lurbinectedin	Topotecan	Chemotherapy
Target Enrollment	~30 Patients	~300 Patients	NA
Details	Evaluating myeloprotection and efficacy	Evaluating OS	Evaluating OS from U.S. Claims data
Sponsor	UNC Lineberger	G1	G1

Initial Overall Survival Data from Real-World Evidence Study[1]



Ongoing clinical studies and real-world-evidence will help guide future development and expansion efforts in ES-SCLC

1. Gajra et al., presented at October 2023 ASCO Quality Care Symposium

Agenda

Unique Marketed Product in U.S. with Growing Revenue

Potential to Transform 1L TNBC Treatment

Opportunity to Improve Safety and Efficacy of Leading ADCs

Positioned for Global Expansion and Future Growth

Metastatic TNBC: Important Area of High Unmet Need

U.S. Patient Populations
(U.S. Market Size Estimates)[1]

1L TNBC
9K Treatable Patients
(~$450M Market Opportunity)

2L TNBC
7K Treatable Patients
(~$350M Market Opportunity)

3L TNBC
5K Treatable Patients
(~$250M Market Opportunity)

Metastatic TNBC is an aggressive cancer with limited treatment options

Cytotoxic therapy remains SoC (+/- immunotherapy based on subpopulation)

Trilaciclib demonstrated broad benefit in 1L/2L/3L TNBC randomized Phase 2
- Benefit observed across PD-L1+ and PD-L1- subpopulations
- Granted Fast Track Designation by FDA for locally advanced or metastatic TNBC

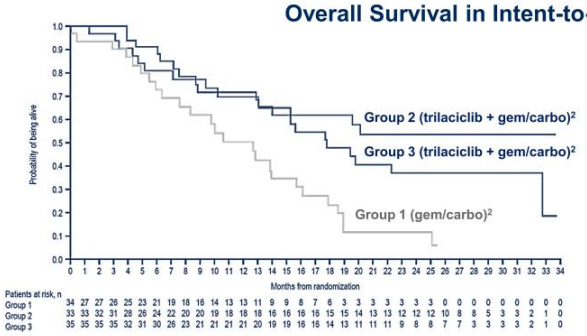
Potential for trilaciclib to transform treatment in metastatic TNBC

G1 THERAPEUTICS

1. Based on Clarivate DRG data, primary market research, and internal analysis to estimate the addressable U.S. population in 2024
2. Market size estimates based on $48,700 current WAC pricing for 32 vials of trilaciclib (mean of ~8 cycles of trilaciclib received in prior mTNBC Phase 2 study)

Observed Robust OS Improvement in Randomized Phase 2[1]

Overall Survival in Intent-to-Treat Population[1]



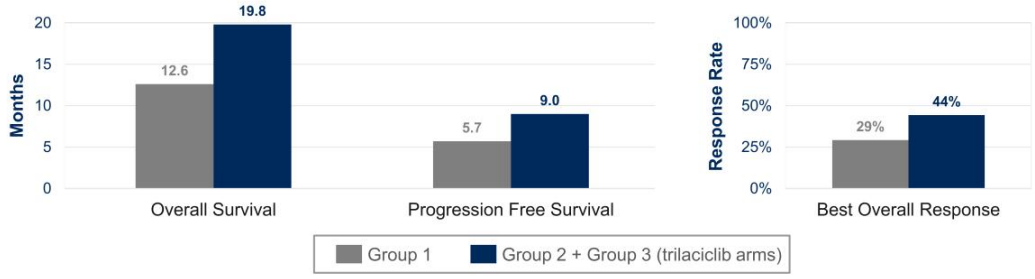
Treatment Group[2]	Median OS, months	Hazard Ratio (95% CI)	*P* Value
Group 1: (gem/carbo)	12.6	-	-
Group 2: (gem/carbo + trilaciclib)	Not Reached	**0.31** (0.15-0.63)	0.0016
Group 3: (gem/carbo + trilaciclib)	17.8	**0.40** (0.22-0.74)	0.0004

Patients in the trilaciclib arms had ~60-70% reduction in the risk of all cause death

1. Tan et al., Clin Cancer Res (2022) 28 (4): 629-636
2. Patients randomized to receive gem/carbo chemotherapy only (Group 1) or gem/carbo plus one of two dosing schedules of trilaciclib: trilaciclib administered on the day of chemotherapy (Group 2) or trilaciclib administered the day prior to and the day of chemotherapy (Group 3).

Overall Survival Most Significant Effect

P-Values	<0.0001	0.1291	0.1859



Trilaciclib demonstrated the most robust effect on OS, consistent with its ability to protect the immune system and improve long-term immune surveillance

1. Tan et al., Clin Cancer Res (2022) 28 (4): 629-636
2. Patients randomized to receive gem/carbo chemotherapy only (Group 1) or gem/carbo plus one of two dosing schedules of trilaciclib : trilaciclib administered on the day of chemotherapy (Group 2) or trilaciclib administered the day prior to and the day of chemotherapy (Group 3).

OS Improvement Observed Across PD-L1 Subpopulations

Overall Survival for Patients with PD-L1 Positive Tumors

	Chemo (Group 1)	Trilaciclib (Groups 2 / 3)
Patients *(n)*	17	32
Median OS *(months)*	**10.5**	**32.7**
HR	**0.34**	
P value	0.004	

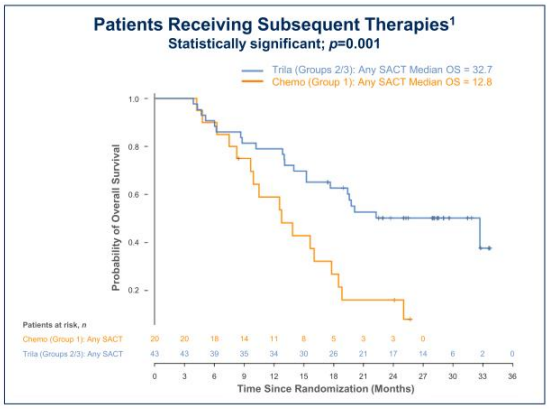
Overall Survival for Patients with PD-L1 Negative Tumors

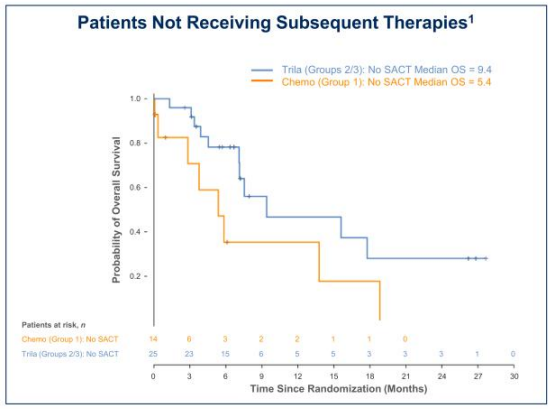
	Chemo (Groups 1)	Trilaciclib (Groups 2 / 3)
Patients *(n)*	10	26
Median OS *(months)*	**13.9**	**17.8**
HR	**0.48**	
P value	0.093	

OS improvement observed regardless of patients' tumor PD-L1 status

1. Tan et al., Clin Cancer Res (2022) 28 (4): 629-636

OS Increased Over Time with Subsequent Therapies



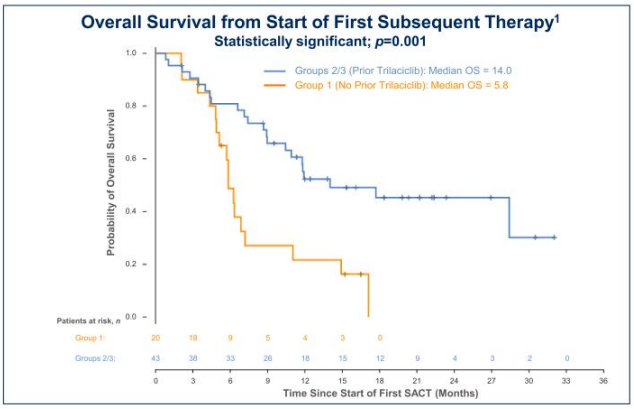


OS benefit continued to increase in the trilaciclib arm as patients received subsequent therapies

Note: SACT: Subsequent Anti-Cancer Therapy.

1. Goel S, Patients with Metastatic Triple-Negative Breast Cancer who Receive trilaciclib prior to cytotoxic chemotherapy exhibit improved survival after receiving subsequent anticancer therapy, San Antonio Breast Cancer Symposium (SABCS), December 5-9, 2023, PO2-06-12.

OS from Start of Subsequent Therapy Exceeds Benchmarks



Subsequent Therapy Administered in Phase 2 (2L+ TNBC)	Median OS[1] (months)
Chemotherapy (Groups 2 / 3 – prior trilaciclib)	**14.0**
Chemotherapy (Group 1 – no prior trilaciclib)	5.8

Historical Benchmarks from ASCENT (2L+ TNBC)	Median OS[2] (months)
Sacituzumab govitecan ("SG")	12.1
Chemotherapy	6.7

Median OS of 14 months from the start of subsequent 2L+ chemotherapy compares favorably to control and historical benchmarks

1. Goel S, Patients with Metastatic Triple-Negative Breast Cancer who Receive trilaciclib prior to cytotoxic chemotherapy exhibit improved survival after receiving subsequent anticancer therapy, San Antonio Breast Cancer Symposium (SABCS), December 5-9, 2023, PO2-06-12.
2. ASCENT data for patients in ASCENT Phase 3 study without brain metastases (from A Bardia, et al., Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer, N Engl J Med 2021; 384:1529-1541).

Ongoing 1L TNBC Phase 3 Builds Upon Phase 2 Results

Evaluating 1L TNBC patients with PD-L1 positive and negative tumors

PRIMARY ENDPOINT:
Overall Survival

SECONDARY ENDPOINTS:
PFS, ORR, PRO, myeloprotection measures

STATUS:
174 Patients Enrolled in mITT[1]
Interim OS Analysis in Q1 2024

Potential to demonstrate trilaciclib + gem/carbo as 1L TNBC standard of care with meaningfully improved OS continuing to increase with subsequent therapies

1. mITT is an adjusted Intent to Treat population for the removal of 13 patients that were enrolled in the study from Ukraine.

Agenda

Unique Marketed Product in U.S. with Growing Revenue

Potential to Transform 1L TNBC Treatment

Opportunity to Improve Safety and Efficacy of Leading ADCs

Positioned for Global Expansion and Future Growth

Clinical Rationale for Combining Trilaciclib with ADCs

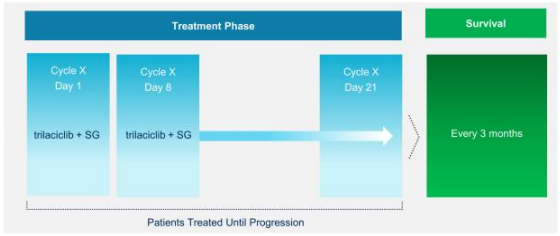
Potential for trilaciclib to meaningfully improve efficacy and safety of leading ADCs

G1 THERAPEUTICS

2L+ TNBC in Combination with SG (“ADC Study”)

Evaluating synergistic combo potential of trilaciclib and sacituzumab govitecan

Single Arm:
2L/3L TNBC



PRIMARY ENDPOINT:
PFS

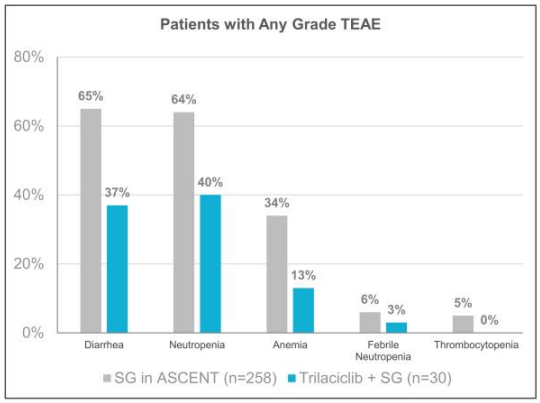
SECONDARY ENDPOINTS:
OS, ORR, CBR,
myeloprotection measures

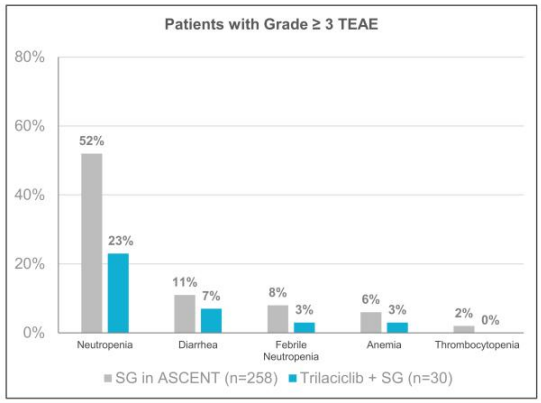
PATIENTS ENROLLED:
30 participants

Strong clinical rationale underlying a trilaciclib + TROP2 ADC combination

G1 THERAPEUTICS

ADC Study Safety and Tolerability





Meaningful reduction in on-target adverse events compared to SG historical data

1. Trilaciclib + SG data from 2Jan2024 data cut; median number of cycles received 6 with 3 patients remaining on study drug
2. ASCENT data for patients in ASCENT Phase 3 study without brain metastases (from A Bardia, et al., Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer, N Engl J Med 2021; 384:1529-1541).

ADC Study Preliminary Efficacy Metrics[1]

	ORR	Median PFS	Clinical Benefit[1]	Median OS
Trilaciclib + SG	23%	4.1 months	47%	17.9 months[2]
SG (Historical from ASCENT[3])	35%	5.6 months	45%	12.1 months

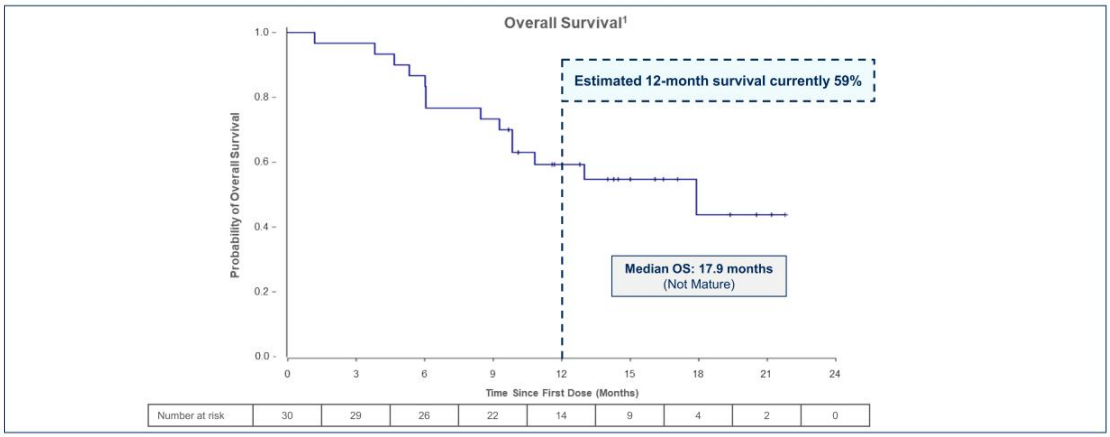
Note: Patients in ongoing ADC Study have relatively similar baseline characteristics as ASCENT with exception of greater prior PD-L1 inhibitor treatment (73% in ongoing ADC study vs. 29% in ASCENT)

Largest benefit expected in OS, consistent with MOA and previous data

Median overall survival for Trilaciclib + SG currently 17.9 months

1. Clinical Benefit calculated as confirmed responses + partial responses + stable disease for at least 6 months
2. Data cutoff for trilaciclib + SG: 4Jan2024 (*OS data not mature*)
3. ASCENT data for patients in ASCENT Phase 3 study without brain metastases (from A Bardia, et al., Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer, N Engl J Med 2021; 384:1529-1541).

ADC Study Preliminary OS (Kaplan-Meier)[1]



Encouraging OS trend with estimated 12-month survival currently 59%; next OS data cut expected mid-2024

1. Data cutoff for trilaciclib + SG: 4Jan2024 (*OS data not mature*)

Agenda

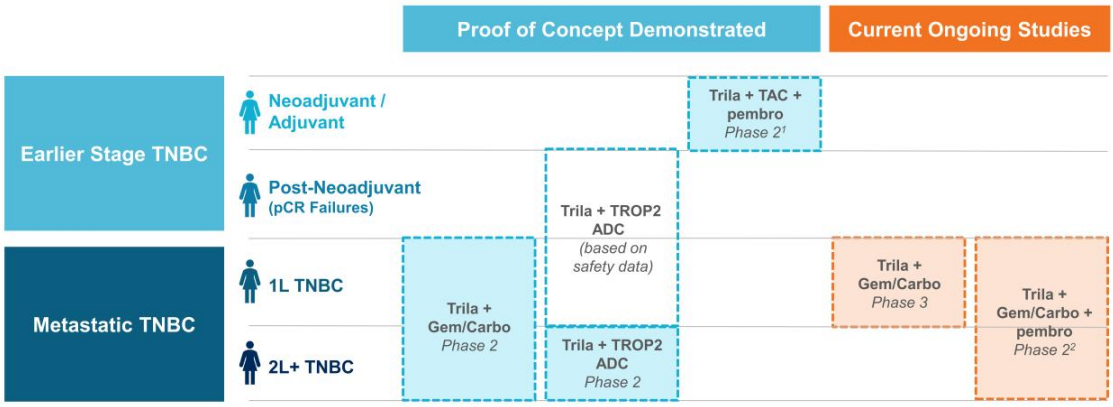
Unique Marketed Product in U.S. with Growing Revenue

Potential to Transform 1L TNBC Treatment

Opportunity to Improve Safety and Efficacy of Leading ADCs

Positioned for Global Expansion and Future Growth

Trilaciclib Well Positioned Across TNBC Treatment Settings



Existing trilaciclib data and ongoing studies to provide roadmap for future commercialization and additional late-stage development opportunities

1. Proof of concept demonstrated in neoadjuvant TNBC patients with PD-L1 positive tumors (given encouraging pCR data in this subpopulation)
2. Phase 2 Investigator Sponsored Study conducted by Atrium Health Levine Cancer Institute

Global Opportunities to be Pursued through Partnership

- Intentionally did not submit filings outside the U.S. and China prior to efficacy data
- TNBC data expected to enable reimbursement in these other territories
- Planning for partnership discussions following successful Ph3 readout

Anticipate successful 1L TNBC data to be catalyst for global expansion plans

G1 THERAPEUTICS

Efficiently Managing Capital with Cash Runway into 2025

Key Capital Allocation Actions Taken in 2023

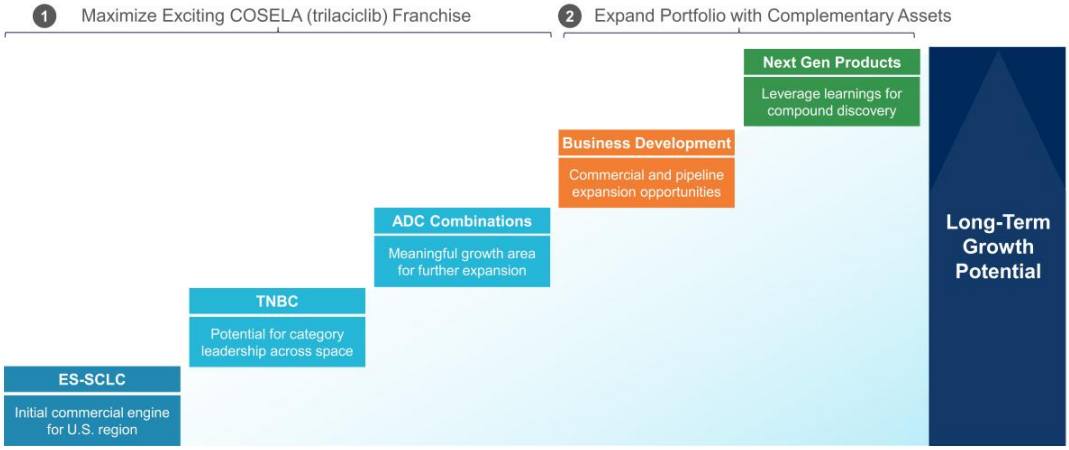
Reduced Operating Expenses	Strengthened Balance Sheet	Increased Financial Flexibility
- Reduced headcount / identified savings - 2023 op-ex over 30% lower than 2022	- Received $27M in net proceeds in sale of Greater China royalties[1] - Potential for additional $18M related to NDA filing / approval of TNBC in China[2]	- Reduced existing debt outstanding from $75M to $50M - Amended loan agreement to alleviate more restrictive cash covenants[3]

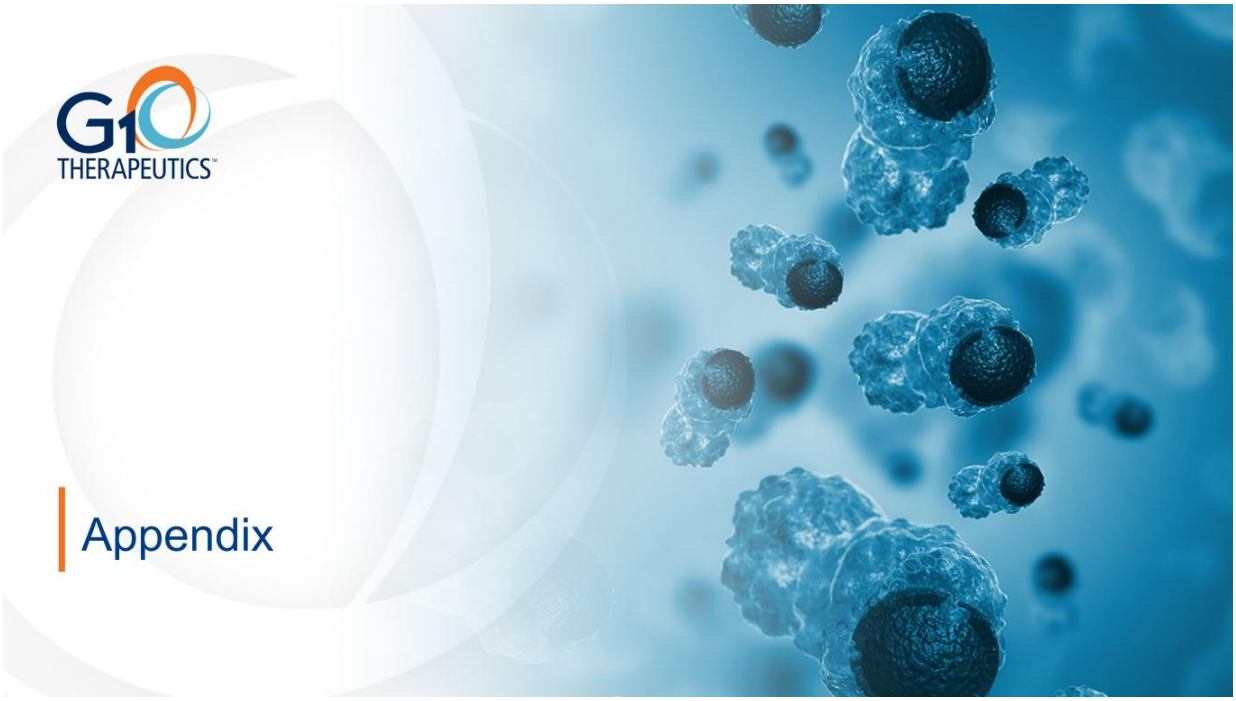
Ended year with increased flexibility and ~$82M in cash, cash equivalents, and marketable securities

Anticipate cash runway into 2025

1. Received $27M in net proceeds after local withholding taxes from partner in China (Simcere) in exchange for relieving them of future royalty payments on sales in Greater China.
2. Potential to receive additional $18M in milestones from Simcere pending NDA filing and approval of a TNBC indication for trilaciclib in China.
3. Amended existing loan agreement with Hercules Capital by lowering minimum cash covenant and removing existing revenue covenant (in exchange for a conditional borrowing base limit)

G1 Focus and Long-Term Vision





Appendix

Recent 2023 Presentations Highlight Benefit of Trilaciclib

American Society of Clinical Oncology (ASCO)
- Reduces adverse events related to ADC
- Immune-mediated MOA protects immune system from ADC damage

European Society for Medical Oncology (ESMO)
- MOA may improve immune surveillance

San Antonio Breast Cancer Symposium (SABCS)
- Highlights clinical impact of trilaciclib MOA
- Patients receiving trilaciclib + chemotherapy prior to subsequent anticancer experience improved survival compared to chemo alone

ASCO Quality Care Symposium (ASCO QC)
- Improved survival in SCLC patients (HR 0.63)
- Odds of severe myelosuppression reduced by >70%
- Lower rate of hospitalizations

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
- Consistent risk of myelosuppression after chemo among patients with SCLC

Medical Meeting Presentations Reinforce Significant Potential for Trilaciclib

2L+ TNBC (“ADC Study”) Patient Baseline Characteristics

Characteristic	Trilaciclib (n=30)	SG in ASCENT (n=235)
Median age, years (range)	56 (30 – 75)	54 (29 – 82)
Female, n (%)	30 (100)	233 (99)
Race, n (%)		
White	26 (87)	188 (80)
Black or African American	3 (10)	28 (12)
Asian	1 (3)	9 (4)
ECOG PS, n (%)		
0	20 (67)	108 (46)
1	10 (33)	127 (54)
Stage at Screening, n (%)		
Locally advanced	2 (7)	NA
Metastatic	28 (93)	NA
TNBC at diagnosis, n (%)	20 (67)	165 (70)
PD-L1 Status, n (%)		
Positive	19 (63)	NA
Negative	8 (27)	NA
BRCA 1/2 mutation status, n (%)		
Negative	17 (57)	133 (57)
Positive	6 (20)	16 (7)
Median previous anticancer regimens, n	3	3
Prior PD-(L)1 treatment, n (%)	22 (73)	67 (29)