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): January 12, 2023

Chimerix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35867**	**33-0903395**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2505 Meridian Parkway, Suite 100
Durham, NC 27713
(Address of principal executive offices, including zip code)

(919) 806-1074
(Registrant's telephone number, including area code)

N/A
(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:

☐ 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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CMRX	The Nasdaq Global Market

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

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 7.01 Regulation FD Disclosure.

On January 12, 2023, Chimerix, Inc. (the "Company") made available an updated corporate presentation (the "Presentation") that the Company intends to use, in whole or in part, in meetings with investors, analysts and others. The Presentation can be accessed through the "Investors" section of the Company's website. A copy of the Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the attached 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, or otherwise subject to the liabilities of that Section. The information in this Item 7.01 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Chimerix, Inc. Corporate Presentation, dated January 12, 2023.
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 hereunto duly authorized.

Date: January 12, 2023

Chimerix, Inc.

By: /s/ Michael T. Andriole
Name: Michael T. Andriole
Title: Chief Business and Financial Officer

Exhibit 99.1

Chimerix, Inc

41st Annual J.P. Morgan Healthcare Conference

January 12, 2023

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Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things: the timing of initiation, progress and completion of ONC201 Phase 3 clinical development; the timing and outcomes of any FDA interactions; the probability of success of our ONC201 development program, and Chimerix's financial strength. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks associated with the sale of TEMBEXA to Emergent; the anticipated benefits of the sale of TEMBEXA may not be realized; the anticipated benefits of the acquisition of Oncoceutics may not be realized; risks that Chimerix's reliance on a sole source third-party manufacturer for drug supply; risks that ongoing or future trials may not be successful or replicate previous trial results; results from historical studies may not be predictive of real-world results or of results in subsequent trials; risks that the benefits from our planned workforce reduction may not be realized; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

Investment highlights

High probability of success for Phase 3 ACTION study of ONC201

- Phase 2 study designed to isolate single agent activity in difficult treatment setting
- Durable responses associated with OS and other forms of clinical benefit
- Numerous independent and natural disease history studies support potential survival advantage
- Genetically selected patient population limits patient heterogeneity

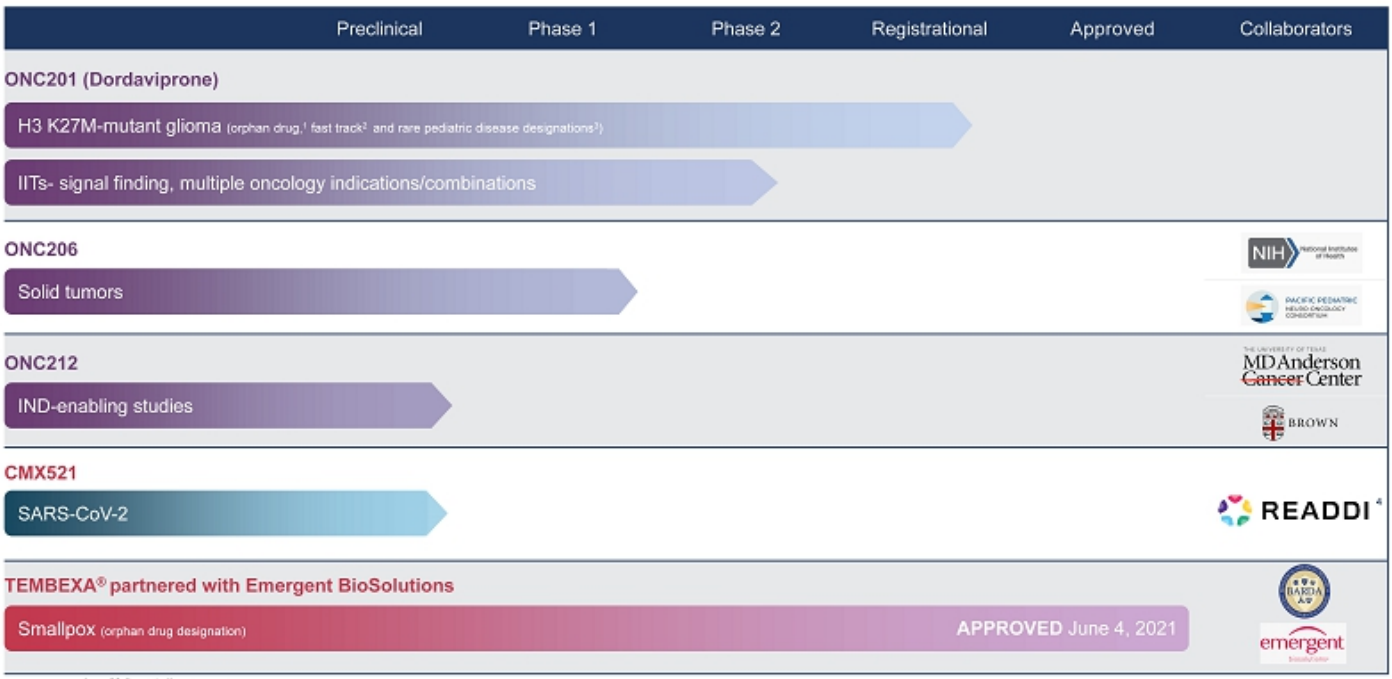
Low barriers to commercial potential for ONC201

- Terminal disease with no effective therapeutic options
- High awareness for program within neuro-oncology community
- U.S. patent exclusivity through at least 2037
- Global revenue potential of ~$750m in first indication alone

Corporate capability and financial flexibility

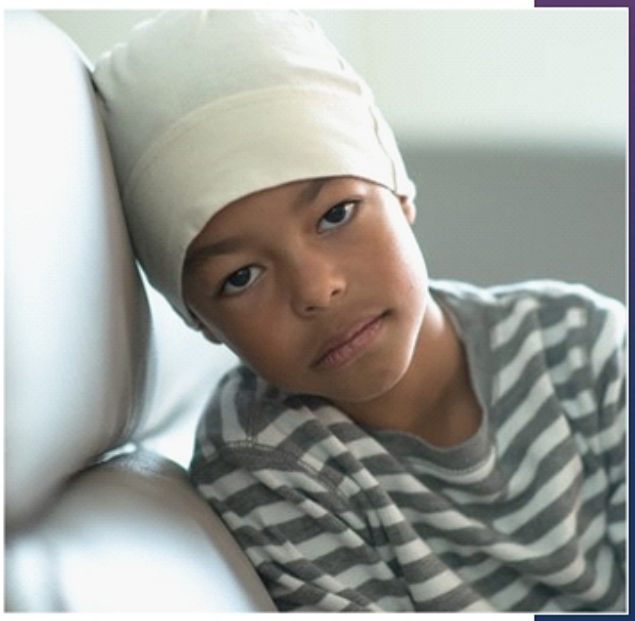
- Leadership team successfully executed large scale studies and regulatory approvals
- Strong balance sheet fully funds ACTION study, leveraged external funding to support pipeline
- Opportunity for continued non-dilutive TEMBEXA milestones and royalties adds flexibility
- Track record of objectivity in creating paths to capture value

Deep pipeline across all development stages



1. Malignant glioma
2. Adult recurrent H3 K27M-mutant high-grade glioma
3. H3 K27M-mutant glioma
4. Rapidly Emerging Antiviral Drug Development Initiative

ONC201 (Dordaviprone) Phase 2 Efficacy Analysis



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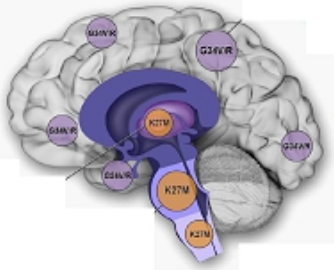
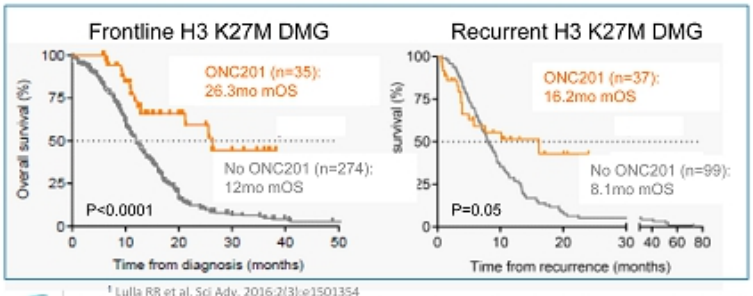
H3 K27M-mutant diffuse glioma: high unmet need

- H3 K27M mutation is predominantly found among diffuse midline gliomas (DMGs) in young adults and children
- Frontline radiotherapy remains standard of care with transient benefit; resection often not feasible
- DMGs harboring the H3 K27M mutation are WHO Grade IV; historically invariably lethal
- Studies consistently indicate longer OS of ONC201-treated glioma patients relative to diverse external controls



Histone H3 Mutations in CNS Tumors[1]

External analysis reported at SNO 2022[2]



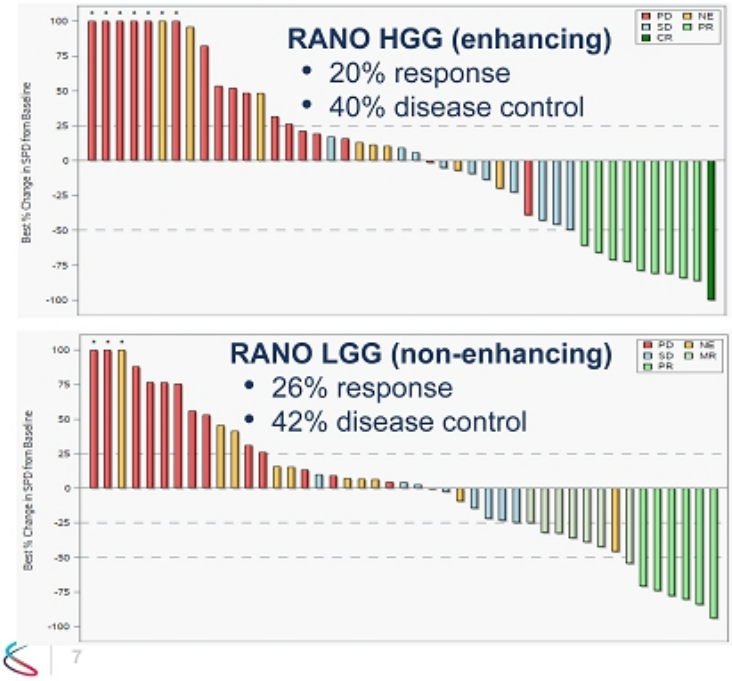
Company Sponsored Studies

	Natural Disease History: Recurrent H3 K27M and/or DMG[3] (n=43)	ONC201 Phase 2: Recurrent H3 K27M DMG (n=50)
Median OS,mo (95% CI)	5.1 (3.9-7.7)	13.7 (8-20.3)
OS @ 12mo (95% CI)	23.6% (11.7-37.9)	57% (41-70)
OS @ 24mo (95% CI)	11.1% (3.3-24.2)	35% (21-49)

[1] Lulla RR et al. Sci Adv. 2016;2(3):e1501354
[2] Sunjong Ji, B.S. et al, "Clinical efficacy and predictive biomarkers of ONC201 in H3 K27M-mutant diffuse midline glioma", Society of Neuro-oncology 2022
[3] The median OS was 5.1 months for the subset of patients with H3 K27M-mutant diffuse glioma excluding DIPG, CSF dissemination, spinal or leptomeningeal disease (N=12), OS at 12 mos was 25.0%, OS at 24 mos was 16.7%

ONC201 waterfall plot – 30% RANO HGG / LGG response

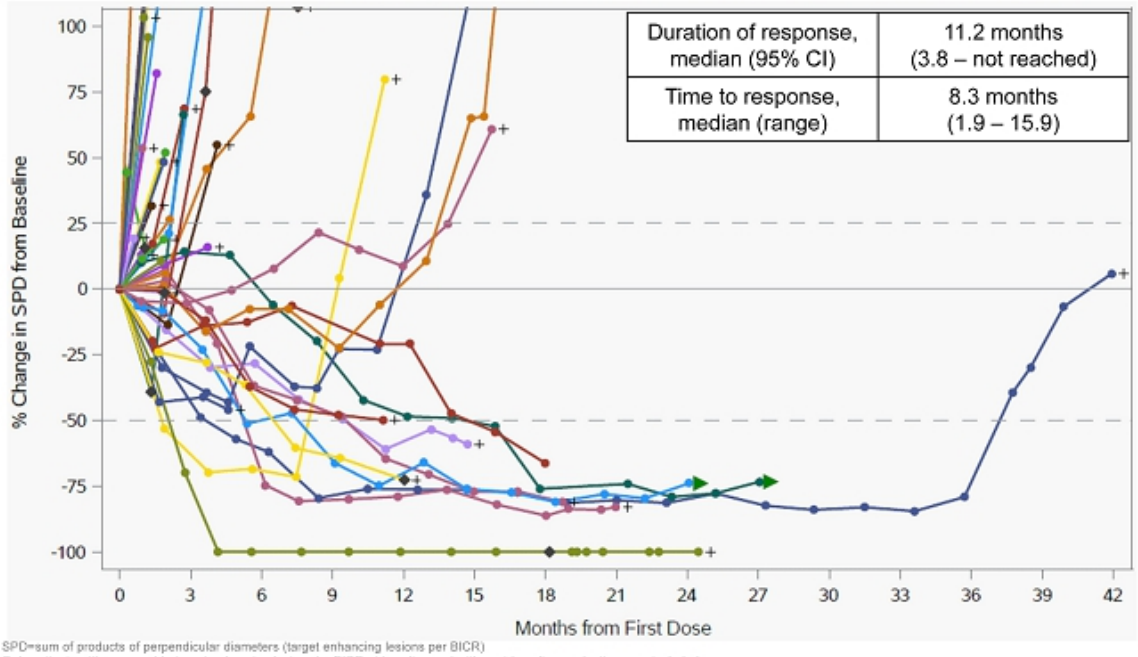
ONC201 Ph 2 Efficacy Analysis by BICR in Recurrent H3 K27M-mutant Diffuse Midline Glioma



- Strict selection criteria to ensure responses attributable to single agent treatment
- Responses require both imaging and clinical criteria
- Dual reader blinded independent central review (BICR)
- Growing consensus that assessment of enhancing and non-enhancing disease (RANO-HGG and RANO-LGG criteria) is needed for diffuse midline glioma

Clinically meaningful and durable RANO-HGG responses

ONC201 Phase 2 Efficacy Analysis by BICR in Recurrent H3 K27M-mutant Diffuse Midline Glioma



SPD=sum of products of perpendicular diameters (target enhancing lesions per BICR)
Only patients with measurable target enhancing lesions by BICR at baseline and with post-baseline evaluations are included.
Three patients did not have on-treatment monotherapy MRIs available for BICR; one patient censored prior to first on-treatment MRI ; one patient did not have measurable target lesion.

ONC201 Safety

Treatment-related Adverse Events in ≥ 3% patients

Treatment-related Adverse Events, Integrated Safety Data Set, (N=211 glioma patients) [1]	Related TEAEs	
	All grades	Grade > 3
Any Treatment-related AE	55.5%	11.8%
Fatigue	21.8%	2.8%
Nausea	20.4%	0
Vomiting	14.2%	0.5%
Headache	8.5%	0.5%
Lymphocyte count decreased	6.6%	0.5%
Decreased appetite	5.7%	0
White blood cell count decreased	4.7%	0.5%
ALT increased	4.3%	0.5%
Hypophosphataemia	4.3%	0
Neutrophil count decreased	3.8%	0.5%
Anaemia	3.3%	0
Diarrhea	3.3%	0

Healthy Adult Study[2]
Incidence of ONC201-related Adverse Events

	125 mg N=33	375 mg N=15	625 mg N=45
Any treatment-related AE	33.0%	20.0%	49.0%
Grade 1	33.0%	20.0%	49.0%
Grade 2	0	0	0
Grade 3-5	0	0	0

- Dose modifications / discontinuations uncommon
- Most common events: headache, fatigue, nausea and vomiting
- Treatment-related AEs generally Grades 1 & 2
- Most common treatment-related event was fatigue

1. Reported in ONC201 Investigator Brochure
2. Preliminary results from ONC201-101, Part A

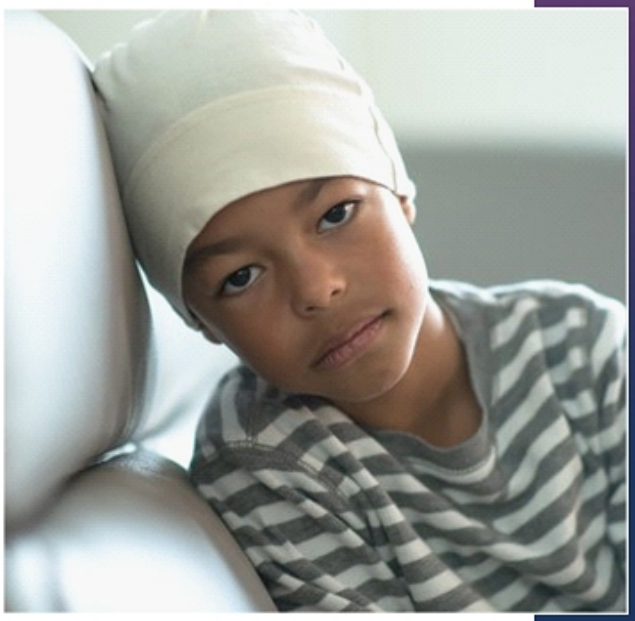
Strong rationale for phase 3 success relative to recent GBM trials

Experimental Agent	Ph2 Design	Biomarker	Response criteria	Confounded by anti-angiogenic pseudo response	ORR	Duration of response	6 month PFS	Approved?
ONC201– Ph2 rDMG	Single agent	H3 K27M	RANO BICR	No	20-30%	11.2	35%	To be determined
Temodal® temozolomide	Single agent	-	Levin	No	5%	?	21%	Yes (OS)
AVASTIN® bevacizumab	Various	-	Various	Yes	20-70%	4-6	18-50%	Yes (AA per ORR, PFS)
Cediranib	Single agent	-	MacDonald	Yes	27%	?	26%	No
Rindopepimut	Combo+ Avastin	EGFRv3	RANO	Yes	30%	7.8	28%	No
Depatuxizumab mafodotin	Single agent	-	RANO	No	7%	6.7	29%	No
Enzastaurin	Combo + Avastin	-	RANO	Yes	22%	?	21%	No

Positive Neutral Negative Characteristics

WKA Yung, et al, British Journal Cancer, Aug 8, 2000; Teri Kreisl, et all, Journal Clinical Oncocloy,2009, Feb 10;27(5):740-5; Tracy Batchelor, et. all, Journal of Clinical Oncology, vol28, issue 17, Jun 10, 2010; David Reardon, et al, Clin Cancer Research Apr 2020; 26(7)1586-1594; Martin van den Bent, et al, Cancer Chemo & Pharma, 26 Oct 2017 80, 1209-1217; Yazmin Odia, et al, Journal Neuro-Oncology 127, 127-125 (2016)

ONC201 Phase 3 ACTION Study Summary



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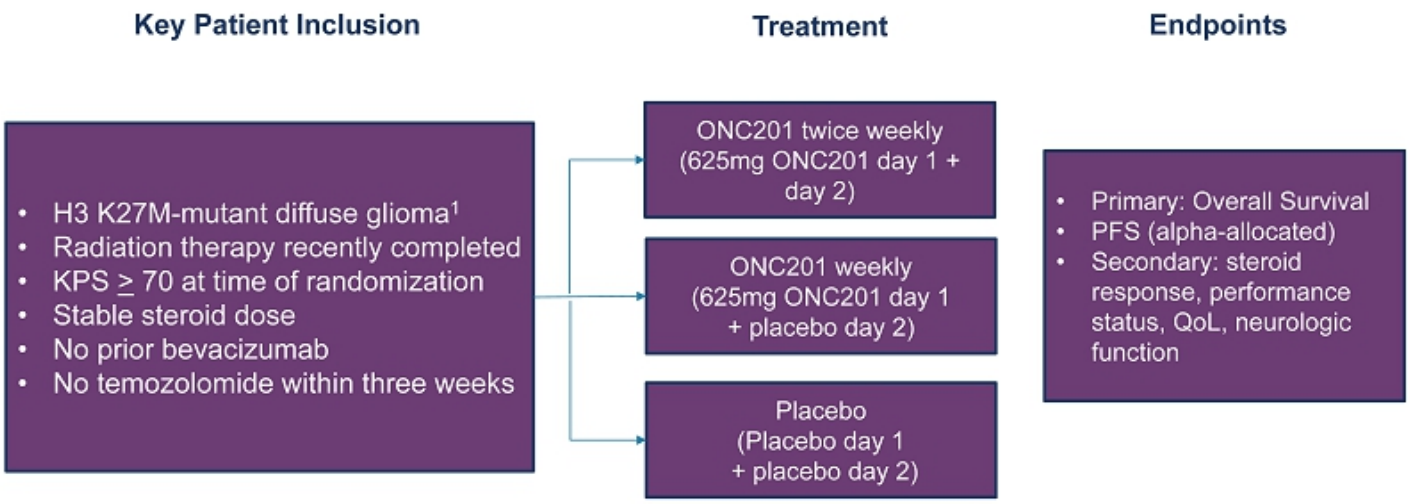
Pivotal Phase 3 ACTION trial design

Now enrolling, a randomized, double-blind, placebo-controlled, multicenter international study in 450 newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation.



1. Excludes DIPG and spinal tumors

Multiple unique aspects to ONC201 data support translation to phase 3 success

Isolated, durable single agent activity

- Responses not confounded by combination treatments
- Responses were gradual, durable, and multi-focul
- Responses observed via most stringent criteria in blinded assessment

Consistency across multiple endpoints

- Responses highly associated with other forms of clinical benefit
- PFS and OS favorable to historical benchmarks
- Multiple separate analyses suggest longer survival of patients who received ONC201

Enhanced activity not required, but likely

- Earlier setting associated with higher response rate (performance status, tumor volume)
- Addition of higher-dose study arm
- Biomarker selection supports patient homogeneity

Design provides multiple paths for success

Interim data expected in early 2025 and final data in 2026

Independent comparisons for each ONC201 arm versus control will be made at each timepoint.

First OS[1] Interim
- ~164 events
- Success at HR[3]=0.52

PFS by RANO HGG[2]
- ~286 events
- Success at HR=0.68

Second OS Interim
- ~246 events
- Success at HR=0.64

Final OS
- ~327 events
- Success at HR=0.73

Powering assumptions 0.65 expected HR for OS and 0.60 expected HR for PFS

1. Overall Survival (OS)
2. Progression-free survival (PFS). PFS may provide valuable data for regulatory discussions.
3. Hazard Ratio

H3 K27M-mutant glioma: rapid ramp to peak revenue expected

- No approved therapies for H3 K27M mutant glioma, ONC201 is the leading program targeting this mutation globally
- Potential market opportunity up to ~$750 million
- Approximately 5,000 patients in top seven markets
- Ultra-orphan indication drug pricing
- H3 K27M mutations most often in children / young adults (little to no exposure to Medicare)
- Low barriers to adoption
  - No effective alternative therapies
  - High unaided awareness among neuro-oncologists
  - Mutation routinely identified by existing diagnostics
  - Longer-term, potentially combinable with other glioma therapies
- Patent protection for lead indication into 2037 - potential U.S. patent term extension (up to five years)

Corporate Update

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Ongoing pipeline development

- ONC206 potentially differentiated DRD2 antagonist + ClpP agonist
  - Enrolling in 2 dose escalation clinical trials for adult and pediatric CNS tumors at NIH[1] and PNOC[2]
- ONC212 GPR132 + ClpP agonist
  - GLP-tox studies ongoing to potentially advance to IND, work performed with support of grant from Brown University
- CMX521 anti-SARS-CoV-2 preclinical activity
  - $2m grant to fund prodrug formulations and research collaboration with University of North Carolina/READDI[3]

1. National Institute of Health
2. Pacific pediatric Neuro-oncology consortium
3. Rapidly Emerging Antiviral Drug Development Initiative

TEMBEXA® deal term summary

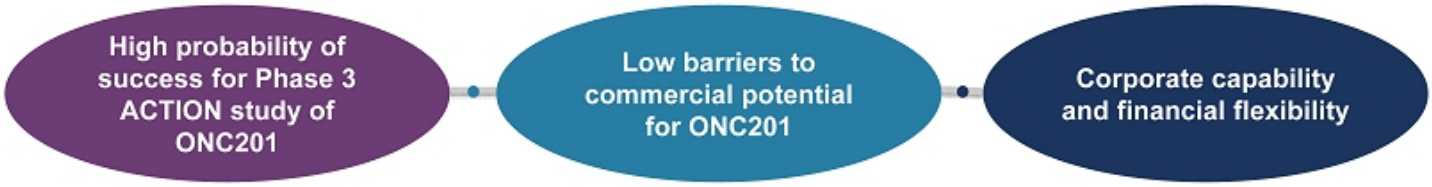
Emergent BioSolutions is an experienced biodefense company collaborating with government agencies to protect public health

Terms summary:

- $238 million received upfront at closing in Q3 2022
- Up to an additional $124 million in potential BARDA procurement milestones
- 20% royalty on future U.S. gross profit with volumes above 1.7 million courses of therapy
- 15% royalty of all international gross profit
- Up to an additional $12.5 million in development milestones

TEMBEXA®
brincidofovir
10 mg/mL oral suspension | 100 mg tablets

Financial strength supports development through key catalysts



$285 million cash balance at September 30, 2022, no debt

Fully funded Ph 3 program with multiple potential paths to approval

First-Line H3 K27M-mutant diffuse glioma – The ACTION Study

- ✓ *Trial initiated November 2022*
- ✓ *Interim OS data expected early 2025*
- ✓ *Full OS data expected 2026*

Early-stage pipeline leverages external capital

- ✓ *ONC206 dose exploration efficacy signal*
- ✓ *Pre-clinical programs potential to advance to clinic or partner (ONC212, CMX521)*
- ✓ *Robust business development search and evaluation process*

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