
**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): August 13, 2026

CANDEL THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40629
(Commission File Number)

52-2214851
(IRS Employer
Identification No.)

**117 Kendrick St
Suite 450
Needham, Massachusetts**
(Address of Principal Executive Offices)

02494
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 916-5445

Not Applicable

(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, \$0.01 par value per share	CADL	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 2.02 Results of Operations and Financial Condition.

On August 13, 2026, Candel Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2026. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is furnished herewith and shall not be deemed “filed” for 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 in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated August 13, 2026
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.

Candel Therapeutics, Inc.

Date: August 13, 2026

By: /s/ Paul Peter Tak

Paul Peter Tak, M.D., Ph.D., FMedSci
President and Chief Executive Officer



Candel Therapeutics Reports Second Quarter 2026 Financial Results and Recent Corporate Highlights

- *Planning to submit a Biologics License Application (BLA) for aglatimagene besadenovec (aglatimagene) in localized, intermediate- to high-risk prostate cancer in Q4 2026*
- *Pivotal phase 3 clinical data published in The Lancet Oncology demonstrated a statistically significant improvement in disease-free survival with aglatimagene plus standard-of-care radiotherapy compared with radiotherapy alone in patients with localized, intermediate- to high-risk prostate cancer*
- *Presented supportive clinical data from extended follow-up of the phase 3 clinical trial of aglatimagene in patients with localized, intermediate- to high-risk prostate cancer in a plenary oral presentation at the American Urological Association (AUA) 2026 Annual Meeting in May 2026*
- *Activated first trial site and open enrollment for a global pivotal phase 3 clinical trial (AURORA), evaluating aglatimagene for patients with stage IV non-squamous non-small cell lung cancer (NSCLC) with progressive disease despite pembrolizumab treatment*
- *Appointed Mark Sims, a seasoned oncology commercial leader with more than 25 years of global and U.S. cancer franchise experience, as Chief Commercial Officer, to support the potential launch of aglatimagene in localized prostate cancer*
- *Advancing to next stage of development planning, with enabling work underway to support a potential randomized phase 2 dose-regimen-finding clinical trial of linoserpaturev in patients with recurrent glioblastoma (rGBM)*
- *Cash and cash equivalents of \$201.6 million, as of June 30, 2026, are expected to be sufficient to fund the Company's current operating plan into Q1 2028, which includes activities to support the potential commercial launch of aglatimagene in 2027*

NEEDHAM, Mass., Aug. 13, 2026 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal immunotherapies to improve outcomes for patients with cancer, today announced financial results for the second quarter ended June 30, 2026, and provided a corporate update.

“This quarter reflects meaningful execution across the company as we advance aglatimagene toward a planned BLA submission in the fourth quarter of 2026 and continue to build the foundation for a potential U.S. commercial launch in localized prostate cancer,” said Paul Peter Tak, M.D., Ph.D., FMedSci, President and CEO of Candel. “We believe the extended follow-up data presented at AUA, together with the publication of our pivotal phase 3 results in *The Lancet Oncology*, further reinforce the potential of aglatimagene to address an important unmet need for patients with intermediate- to high-risk localized prostate cancer. At the same time, the activation of the first trial site for the AURORA phase 3 clinical trial in patients with advanced NSCLC underscores the broader potential of our multimodal immunotherapy platform across solid tumors.”

Dr. Tak continued, “We also made important progress in commercial readiness through our appointment of Mark Sims as Chief Commercial Officer, adding deep oncology commercialization and launch experience as we prepare for the next stage of Candel’s growth. With a strong balance sheet, we believe we are well-positioned to execute our operating plan into the first quarter of 2028, including activities intended to support a potential U.S. commercial launch of aglatimagene in 2027, if approved.”

Second Quarter 2026 & Recent Highlights

- *Aglatimagene besadenovec – Prostate Cancer*
 - The Company continues to advance its pre-BLA readiness initiative, including its Chemistry, Manufacturing, and Controls (CMC) activities, preparation of clinical study reports, and BLA modules.
 - Process validation campaign for drug substance and drug product is being executed at our contract development and manufacturing organization. The campaign is progressing well and is a critical CMC activity to enable the anticipated BLA submission in Q4 2026.
 - New clinical material has been produced and is intended to be used in the pivotal phase 3 clinical trial of aglatimagene in NSCLC.
 - The Company published results from the randomized, double-blind, placebo-controlled, multicenter pivotal phase 3 clinical trial of aglatimagene in patients with intermediate- to high-risk localized prostate cancer in *The Lancet Oncology*. These data were initially announced in December 2024 and presented as an oral presentation at ASCO 2025.
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- The Company presented clinical data from extended follow-up of its phase 3 trial of aglatimagene in prostate cancer in a plenary oral presentation at the AUA 2026 Annual Meeting, held in Washington, D.C. from May 15-18, 2026.
 - Among the 745 patients enrolled in the randomized, double-blind, placebo-controlled trial, the aglatimagene arm exhibited a 39% improvement in prostate cancer-specific disease-free survival (PCa-specific DFS) compared to placebo after a median follow-up of 58 months (data as of March 15, 2026).
 - The Company observed consistently favorable trends in both the intent to treat and intermediate-risk subgroup populations across all secondary and exploratory endpoints, including time to biochemical failure, time to metastasis, rate of metastasis, and time to salvage anti-cancer therapy (time to new treatment), when comparing the aglatimagene arm with placebo, on top of standard-of-care radiotherapy.
 - There were no new safety signals or additional toxicities observed.

For additional information, please refer to Candela's May 15, 2026, press release.

- The Company will present an abstract delineating extended biomarker analysis from the phase 3 clinical trial of aglatimagene in patients with localized prostate cancer at the 2026 American Society for Radiation Oncology (ASTRO) Annual Meeting in Q3 2026.
 - The U.S. Food and Drug Administration (FDA) previously granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to aglatimagene for the treatment of localized prostate cancer. The phase 3 clinical trial of aglatimagene in localized prostate cancer was conducted under a Special Protocol Assessment with respect to certain aspects of the study design, agreed with the FDA.
 - *Aglatimagene besadenovec – Non-Small Cell Lung Cancer (NSCLC)*
 - In June 2026, the Company activated the first clinical trial site of the global pivotal phase 3 clinical trial (AURORA) (NCT07660094), which will evaluate aglatimagene plus valacyclovir in combination with continued pembrolizumab in patients with metastatic non-squamous NSCLC whose disease has progressed despite treatment with pembrolizumab and platinum-based chemotherapy.
 - The randomized, open-label AURORA trial is expected to enroll patients with metastatic stage IV non-squamous NSCLC across approximately 150 sites worldwide, randomized 1:1 to receive either two courses of
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aglatimagene plus valacyclovir with continued pembrolizumab or standard-of-care docetaxel chemotherapy.

- The study's primary endpoint is overall survival, with secondary endpoints including safety and quality-of-life assessments (NSCLC-SAQ and EORTC QLQ-30).
- The FDA previously granted Fast Track Designation to aglatimagene for the treatment of NSCLC.
- *Linoserpaturev - Recurrent Glioblastoma (rGBM)*
 - Following FDA clearance of its Investigational New Drug application for linoserpaturev in Q1 2026, the Company is advancing next-stage development planning for rGBM.
 - Enabling work is underway to support a potential randomized phase 2 dose-regimen-finding study.
 - The clinical trial is expected to inform the optimal number of linoserpaturev administrations and a recommended regimen for future development.
- *Recent Corporate Events*
 - In June 2026, the Company appointed Mark Sims as Chief Commercial Officer. Mr. Sims is a seasoned oncology commercial leader with more than 25 years of experience building and advancing Global and U.S. cancer franchises. He held key leadership roles at AstraZeneca PLC, Novartis AG, and Idenix Pharmaceuticals, Inc.. Mr. Sims' appointment strengthens the Company's efforts toward its planned BLA submission in the fourth quarter of 2026 and potential 2027 launch of aglatimagene in localized prostate cancer.
 - In April 2026, the Company announced a commercialization agreement with EVERSANA® to support the potential U.S. launch of aglatimagene in localized prostate cancer. This operating model gives Candel immediate access to leading commercial capabilities, while maintaining financial flexibility, capital efficiency, and scientific focus that has driven the Company's progress to date.

Anticipated Milestones

- Abstract showcasing extended biomarker data from the phase 3 clinical trial of aglatimagene in patients with localized prostate cancer to be presented as a poster at the ASTRO Annual Meeting in Q3 2026.
 - The Company expects to present potential long-term survival data from arm C of its phase 1b clinical trial of linoserpaturev in patients with recurrent high-grade glioma (rHGG) in Q4 2026.
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- Submission of a BLA for aglatimagene in prostate cancer is planned for Q4 2026.

Financial Results for the Second Quarter Ended June 30, 2026

Research and Development Expenses: Research and development expenses were \$19.8 million for the second quarter of 2026 compared to \$7.0 million for the second quarter of 2025. The increase was primarily due to higher clinical trial and manufacturing costs, in support of the Company's aglatimagene programs, and an increase in employee-related expenses. Research and development expenses included a non-cash stock compensation expense of \$1.8 million for the second quarter of 2026, as compared to a non-cash stock compensation expense of \$0.4 million for the second quarter of 2025.

General and Administrative Expenses: General and administrative expenses were \$6.9 million for the second quarter of 2026, compared to \$4.2 million for the second quarter of 2025. The increase was primarily due to higher commercial readiness costs and an increase in employee-related expenses. General and administrative expenses included non-cash stock compensation expense of \$1.0 million for the second quarter of 2026, as compared to a non-cash stock compensation expense of \$0.6 million for the second quarter of 2025.

Net Income/Loss: Net loss for the second quarter of 2026 was \$38.9 million compared to net loss of \$4.8 million for the second quarter of 2025 and included net other expense of \$12.2 million and net other income of \$6.4 million, respectively. The increase in net other expense was primarily related to the change in the fair value of the Company's warrant liabilities.

Cash Position: Cash and cash equivalents, as of June 30, 2026, were \$201.6 million compared to \$119.7 million as of December 31, 2025. Based on current operating plans, the Company expects that its existing cash and cash equivalents, as of June 30, 2026, will be sufficient to fund operations into Q1 2028.

About aglatimagene besadenovec

Aglatimagene, Candel's most advanced multimodal biological immunotherapy candidate, is an investigational, off-the-shelf, replication-defective adenovirus designed to deliver the herpes simplex virus thymidine kinase (HSV-tk) gene to a patient's tumor. After intratumoral administration, HSV-tk enzyme activity results in conversion of prodrug (valacyclovir) into deoxyribonucleic acid (DNA)-incorporating nucleotide analogs, leading to immunogenic cell death in cells exhibiting DNA damage and proliferating cells, with subsequent release of a variety of tumor (neo)antigens in the tumor microenvironment. At the same time, the adenoviral serotype 5 capsid proteins promote inflammation through the induction of expression of pro-inflammatory cytokines, chemokines, and adhesion molecules. Together, this regimen is designed to induce an individualized and specific CD8+ T cell-mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity, based on in situ immunization against a variety

of tumor antigens. Aglatimagene has the potential to treat a broad range of solid tumors. Encouraging monotherapy activity as well as combination activity with standard of care radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitors have previously been shown in several preclinical and clinical settings. More than 1,000 patients have been dosed with aglatimagene in clinical trials with a favorable tolerability profile to date, supporting the potential for use with standard of care, when indicated. Aglatimagene is currently not approved by the FDA or any other regulatory authority for any use.

About linoserpaturev

Linoserpaturev is a first-in-class, replication-competent, next-generation oncolytic herpes simplex virus-1 (HSV-1) immunotherapy candidate designed for dual activity for oncolysis and immune activation in a single therapeutic. In October 2023, the Company announced that *Nature* published results from the ongoing clinical trial where linoserpaturev was reported to be generally well tolerated with no dose-limiting toxicity. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single linoserpaturev injection in this therapy-resistant condition¹. The Company and academic collaborators are currently supported by the Break Through Cancer foundation to evaluate the effects of repeated linoserpaturev injections in patients with recurrent glioblastoma in an expansion cohort from the phase 1b clinical trial. In October 2025, *Science Translational Medicine* presented findings from the comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of linoserpaturev in arm C. Linoserpaturev previously received Fast Track Designation and Orphan Drug Designation for the treatment of rHGG from the U.S. Food and Drug Administration (FDA).

About Candel Therapeutics

Candel is a clinical-stage biopharmaceutical company focused on developing off-the-shelf multimodal biological immunotherapies that elicit an individualized, systemic anti-tumor immune response to help improve outcomes in patients with cancer. Candel has established two clinical-stage multimodal biological immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) gene constructs, respectively. Aglatimagene besadenovec (aglatimagene) is the lead product candidate from the adenovirus platform. The Company completed successful phase 2a clinical trials of aglatimagene in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of aglatimagene in localized prostate cancer, conducted under a Special Protocol Assessment agreed with the FDA and published in *The Lancet Oncology*. The Company has also initiated a pivotal phase 3 clinical trial in NSCLC. The FDA granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to aglatimagene for the treatment of newly diagnosed localized prostate cancer in patients with intermediate- to high-risk disease, Fast Track Designation in NSCLC, and both Fast Track Designation and Orphan Drug Designation to aglatimagene for the treatment of PDAC.

Linoserpaturev is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in rHGG. Finally, Candel's enLIGHTEN™ Discovery

Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new viral immunotherapies for solid tumors.

For more information about Candel, visit: www.candeltx.com.

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements,” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the timing and advancement of current and future development programs, including the timing and availability of additional data and key data readout milestones and presentations; expectations regarding the submission of the BLA for aglatimagene in intermediate- to high-risk localized prostate cancer; expectations regarding enrollment of the phase 3 AURORA trial evaluating aglatimagene in NSCLC; expectations regarding early biological readouts as predictor of clinical response; expectations regarding the therapeutic benefit of the Company’s platforms, including the ability of its platforms to improve overall survival and/or disease-free survival of patients living with difficult-to-treat solid tumors; expectations regarding the potential benefits conferred by regulatory designations; expectations regarding the potential benefits conferred by the publication of the Company’s findings in *The Lancet Oncology*; expectations regarding the Company’s ability to prepare and implement commercialization plans for aglatimagene (if approved); and expectations regarding cash runway and expenditures. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of development programs; expectations regarding the therapeutic benefit of the Company’s programs; that final data from the Company’s preclinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; the Company’s ability to efficiently discover and develop product candidates; the Company’s ability to obtain and maintain regulatory approval of product candidates; the Company’s ability to maintain its intellectual property; the implementation of the Company’s business model, including strategic plans for the Company’s business and product candidates; the impact of the Company’s existing and any future indebtedness on its ability to operate its business; the Company’s ability to access any future tranches under its debt facility and to comply with all of its obligations thereunder; and other risks identified in the Company’s filings with the U.S. Securities and Exchange Commission (SEC), including the Company’s most recent Annual Report on Form 10-K, any subsequent Quarterly Reports on Form 10-Q, and any subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any

change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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¹ Ling AL, et al. Nature. 2023;623(7985):157-166

Candel Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 19,801	\$ 6,991	\$ 29,641	\$ 11,007
General and administrative	6,945	4,186	13,389	8,300
Total operating expenses	<u>26,746</u>	<u>11,177</u>	<u>43,030</u>	<u>19,307</u>
Loss from operations	<u>(26,746)</u>	<u>(11,177)</u>	<u>(43,030)</u>	<u>(19,307)</u>
Other income (expense):				
Grant income	22	—	44	—
Interest income	1,672	926	2,994	1,860
Interest expense	(1,575)	(236)	(3,139)	(542)
Change in fair value of warrant liabilities	(12,278)	5,691	(4,635)	20,572
Total other income (expense), net	<u>(12,159)</u>	<u>6,381</u>	<u>(4,736)</u>	<u>21,890</u>
Net income (loss) and comprehensive income (loss)	<u>\$ (38,905)</u>	<u>\$ (4,796)</u>	<u>\$ (47,766)</u>	<u>\$ 2,583</u>
Net income (loss) per share, basic	<u>\$ (0.52)</u>	<u>\$ (0.09)</u>	<u>\$ (0.70)</u>	<u>\$ 0.05</u>
Weighted-average common shares outstanding, basic	<u>74,131,229</u>	<u>51,489,929</u>	<u>68,279,075</u>	<u>50,988,887</u>
Net income (loss) per share, diluted	<u>\$ (0.52)</u>	<u>\$ (0.09)</u>	<u>\$ (0.70)</u>	<u>\$ 0.05</u>
Weighted-average common shares outstanding, diluted	<u>74,131,229</u>	<u>51,489,929</u>	<u>68,279,075</u>	<u>53,369,582</u>

Candel Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)

	JUNE 30, 2026 (Unaudited)	DECEMBER 31, 2025
Cash and cash equivalents	\$ 201,565	\$ 119,731
Working capital (1)	191,473	112,392
Total assets	208,149	125,195
Warrant liabilities	20,233	15,598
Total other liabilities	61,786	57,675
Accumulated deficit	(278,153)	(230,387)
Total stockholders' equity	\$ 126,130	\$ 51,922

(1) Working capital is calculated as current assets less current liabilities

