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 14, 2023

Arcellx, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41259**	**47-2855917**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

25 West Watkins Mill Road **Suite A** **Gaithersburg, Maryland**	**20878**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 240 327-0603

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, $0.001 par value per share	ACLX	The Nasdaq Stock Market LLC

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 14, 2023, Arcellx, Inc. (the "Company") issued a press release announcing the Company's financial results for the fiscal quarter ended June 30, 2023. A copy of the Company's press release is attached hereto as Exhibit 99.1.

The information furnished pursuant to Item 2.02 on this Form 8-K, including Exhibit 99.1 attached hereto, 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 into any other 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 No.	Description
99.1	Press Release dated August 14, 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.

Arcellx, Inc.

Date: August 14, 2023

By: /s/ Rami Elghandour

Rami Elghandour
Chief Executive Officer

Exhibit 99.1

Arcellx Announces Partial Clinical Hold Lifted on iMMagine-1 Phase 2 Clinical Program and Reports Second Quarter Financial Results

-- Company expects to present preliminary data from iMMagine-1 study in 2H'24 --

REDWOOD CITY, Calif., August 14, 2023 /PRNewswire/ -- Arcellx, Inc. (NASDAQ: ACLX), a biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases, today announced the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold placed on the company's CART-ddBCMA investigational new drug for the treatment of patients with relapsed or refractory multiple myeloma (rrMM) and reported financial results for the second quarter ended June 30, 2023.

"We have worked closely with FDA to expeditiously resolve the clinical hold and we thank them for their collaboration and dialogue throughout this process," said Rami Elghandour, Arcellx's Chairman and Chief Executive Officer. "During the review process, we updated our trial protocol, and were pleased that FDA allowed for expanded bridging therapies, which better aligns our protocol with current clinical practice. As a key step to enhancing protocol adherence related to the prevention and management of the risk of adverse events, we retrained clinical sites. Importantly, during the partial clinical hold, FDA approved dosing of all 17 patients who had been enrolled but not yet dosed prior to the hold, minimizing treatment disruption for patients and clinicians. We and our partners at Kite remain confident in CART-ddBCMA's potential as a best-in-class therapy for the treatment of patients with rrMM given the totality of data to date across our studies. We have a strong balance sheet funding operations through BLA filing and into 2026. We look forward to presenting data from our Phase 1 study later this year as well as preliminary data from the iMMagine-1 study in the second half of 2024. Additionally, we continue to expect commercial launch of CART-ddBCMA to be in 2026."

Recent Business Progress

Announced clinical hold and clinical hold lifted by FDA for the company's iMMagine-1 Phase 2 Clinical Program. On June 19, 2023, Arcellx announced that its iMMagine-1 study had been placed on partial clinical hold by FDA following a recent patient death, which involved a patient who was treated with CART-ddBCMA despite becoming ineligible for treatment under the trial protocol prior to CART-ddBCMA infusion. Subsequently, the patient was managed in a manner that conflicted with the trial protocol. On August 14, 2023, Arcellx announced that FDA had lifted the partial clinical hold after aligning with FDA on modifications to the iMMagine-1 trial protocol related to the prevention and management of the risk of adverse events within the trial. As a key effort to enhance protocol adherence, Arcellx retrained clinical sites. Additionally, FDA allowed an expansion of treatment options for therapies that patients in the iMMagine-1 trial are permitted to receive between apheresis and CAR-T infusion (also known as bridging therapies) to better align its protocol with current clinical practice. The company anticipates presenting preliminary data from the iMMagine-1 study in the second half of 2024.

Second Quarter 2023 Financial Highlights

Cash, cash equivalents, and marketable securities:
As of June 30, 2023, Arcellx had cash, cash equivalents, and marketable securities of $506.5 million. Arcellx anticipates that its cash, cash equivalents, and marketable securities will fund its operations into 2026.

Collaboration revenue:
Collaboration revenue was $14.3 million and $0 for the quarters ended June 30, 2023 and 2022, respectively. The revenue results for the three months ended June 30, 2023 is from the recognition of research and development performed under the arrangement described in the recent license and collaboration agreement with Kite Pharma, Inc. (Kite). Revenue is being recognized on a percentage of completion basis over the term of the contract with Kite.

R&D expenses:
Research and development expenses were $28.3 million and $22.1 million for the quarters ended June 30, 2023 and 2022, respectively, an increase of $6.2 million. This increase was primarily driven by higher external costs associated with the advancement of the company's CART-ddBCMA clinical program and personnel.

G&A expenses:
General and administrative expenses were $15.5 million and $9.2 million for the quarters ended June 30, 2023 and 2022, respectively, an increase of $6.3 million. This increase was driven by primarily by personnel and professional fees.

Net loss:
Net loss was $23.9 million and $30.8 million for the quarters ended June 30, 2023 and 2022, respectively.

About Arcellx, Inc.
Arcellx, Inc. is a clinical-stage biotechnology company reimagining cell therapy by engineering innovative immunotherapies for patients with cancer and other incurable diseases. Arcellx believes that cell therapies are one of the forward pillars of medicine and Arcellx's mission is to advance humanity by developing cell therapies that are safer, more effective, and more broadly accessible. Arcellx's lead product candidate, CART-ddBCMA, is being developed for the treatment of relapsed or refractory multiple myeloma (rrMM) in a Phase 2 pivotal trial. CART-ddBCMA has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy designations by the U.S. Food and Drug Administration.

Arcellx is also advancing its dosable and controllable CAR-T therapy, ARC-SparX, through two clinical-stage programs: a Phase 1 study of ACLX-001 for rrMM, initiated in the second quarter of 2022; and ACLX-002 in relapsed or refractory acute myeloid leukemia and high-risk myelodysplastic syndrome, initiated in the fourth quarter of 2022. For more information on Arcellx, please visit www.arcellx.com. Follow Arcellx on X (formerly Twitter, @arcellx) and LinkedIn.

About Arcellx and Kite Pharma Collaboration
Arcellx and Kite, a Gilead Company, recently formed a global strategic collaboration to co-develop and co-commercialize Arcellx's CART-ddBCMA candidate for the treatment of patients with relapsed or refractory

multiple myeloma currently in a pivotal Phase 2 study. Kite and Arcellx will jointly advance and commercialize the CART-ddBCMA asset in the United States, and Kite will commercialize the product outside the U.S.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this press release that are not purely historical are forward-looking statements, including Arcellx's plans for the clinical development of its product candidates, including anticipated announcements of additional data; expected timeline for commercial launch of its lead product candidate, if approved by FDA; Arcellx and Kite's plans to advance and commercialize CART-ddBCMA; and the sufficiency of cash, cash equivalents and marketable securities and its ability to fund operations through certain regulatory milestones and timelines. The forward-looking statements contained herein are based upon Arcellx's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including risks that may be found in the section entitled Part II, Item 1A (Risk Factors) in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission (SEC) on or about the date hereof, and the other documents that Arcellx may file from time to time with the SEC. These forward-looking statements are made as of the date of this press release, and Arcellx assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

ARCELLX, INC.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 506,484	$ 254,835
Total assets	623,528	313,817
Total liabilities	329,861	108,863
Total stockholders' equity	293,667	204,954

ARCELLX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	$ 14,302	$ —	$ 32,213	$ —
Operating expenses:				
Research and development	28,327	22,083	61,258	40,139
General and administrative	15,535	9,207	30,972	17,241
Total operating expenses	43,862	31,290	92,230	57,380
Loss from operations	(29,560)	(31,290)	(60,017)	(57,380)
Other income, net	5,424	518	8,866	567
Loss before income taxes	(24,136)	(30,772)	(51,151)	(56,813)
Income tax provision (benefit)	(282)	-	47	-
Net loss	(23,854)	(30,772)	(51,198)	(56,813)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	(93)	(218)	214	(242)
Comprehensive loss	$ (23,947)	$ (30,990)	$ (50,984)	$ (57,055)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.50)	(0.84)	$ (1.08)	(1.98)
Weighted-average common shares outstanding—basic and diluted	48,106,528	36,609,772	47,441,647	28,729,029

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