

**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): **November 10, 2022**

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37998
(Commission
File Number)

45-4870634
(IRS Employer
Identification No.)

780 Memorial Drive
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(Zip Code)

Registrant's telephone number, including area code: **(857) 259-3840**

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 (*see* General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	JNCE	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 November 10, 2022, Jounce Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended September 30, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (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 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 issued by the Company on November 10, 2022
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.

JOUNCE THERAPEUTICS, INC.

Date: November 10, 2022

By: /s/ Kim C. Drapkin
Kim C. Drapkin
Treasurer and Chief Financial Officer

Jounce Therapeutics Reports Third Quarter 2022 Financial Results

- *INNATE trial of JTX-8064 +/- pimivalimab Phase 1 Dose Escalation data at ESMO-IO Annual Congress -*
- *SELECT randomized trial of pimivalimab +/- vopratelimab phase 2 data at ESMO-IO Annual Congress -*
- *Two preclinical posters on JTX-1484 and LILRB family at SITC 2022 -*
- *Ended the quarter with \$130.3 million in cash, cash equivalents and investments -*
- *Company to host conference call and webcast today at 8:00 AM ET -*

CAMBRIDGE, Mass., November 10, 2022 - Jounce Therapeutics, Inc. (NASDAQ: JNCE), a clinical-stage company focused on the discovery and development of novel cancer immunotherapies and predictive biomarkers, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

“We have continued to execute across our pipeline of innovative immunotherapy candidates in the third quarter, especially in the Phase 2 cohorts of the INNATE study. We are proud to be sharing multiple sets of data from our discovery and development programs at two important immuno-oncology conferences this year,” said Richard Murray, Ph.D., chief executive officer and president of Jounce Therapeutics. “Our goal is to strive for a meaningful immunotherapy for patients who have few options. This is at the heart of our approach to developing novel mechanisms guided by biomarkers.”

Pipeline Update & Highlights:

JTX-8064 (LILRB2/ILT4)

- **INNATE Phase 1 dose escalation data to be presented at ESMO Immuno-Oncology Congress.** A poster will be presented on the Phase 1 dose escalation data, including all 31 Phase 1 dose escalation patients, at the European Society of Medical Oncology Immuno-Oncology Annual Congress 2022 (ESMO-IO) being held from December 7-9 in Geneva, Switzerland. Data presented will include safety, pharmacokinetics, receptor occupancy, and preliminary efficacy data.
- **Continued to advance INNATE Phase 2 trial across multiple indications.** Jounce is evaluating JTX-8064 in the ongoing Phase 2 portion of the INNATE clinical trial, which is comprised of indication specific expansion cohorts, including one monotherapy cohort and initially seven cohorts in combination with pimivalimab (pimi), the Jounce PD-1 inhibitor. Each combination cohort is a Simon’s 2-stage design, enrolling 10 patients for an initial assessment of response, and then enrolling to a total of 29 patients if prespecified response criteria are met. Today, Jounce is announcing that enrollment of the first 10 patients has been completed in all 7 phase 2 combination cohorts. Updates on the status of combination cohorts include: 1) Stage 1 criteria met for PD-1 or PD-L1 (PD-(L)1) inhibitor resistant 2L/3L head and neck squamous cell carcinoma (HNSCC), currently under review for expansion, 2) Stage 1 criteria not met for PD-(L)1 inhibitor naïve sarcoma, 3) Two combination cohorts, in 1L PD-(L)1 inhibitor naïve HNSCC and PD-(L)1

inhibitor resistant cutaneous squamous cell carcinoma, along with the ovarian monotherapy cohort, still have the potential to meet criteria to advance from Stage 1 to Stage 2. Jounce also announces that enrollment has started in a new combination cohort in PD-(L)1 inhibitor resistant 2L/3L biliary tract cancer (BTC), informed by a confirmed durable response in Phase 1 in combination with pimi. In the Phase 2 cohorts that had previously met the criteria to expand, the ovarian cohort has over-enrolled with 35 patients, and the renal cell cohort is nearing complete enrollment with 26 of 29 patients enrolled.

- **Jounce now expects to be in position to share additional results from the phase 2 portion of the study in the first half of 2023, instead of ESMO-IO in December 2022.** In the preliminary data in over 80 patients across all combination cohorts, Jounce believes it has seen signs of clinical activity of JTX-8064 but not broad activity leading to rapid proof-of-concept (POC). Efficacy data is taking time to mature, and assessment of whether POC will be achieved, based on confirmed responses in each fully expanded cohort, will enable the presentation of a complete and interpretable data set. Both the JTX-8064 monotherapy and pimi combination continue to demonstrate an acceptable safety profile to date.

Vopratelimab (ICOS) and Pimivalimab (PD-1)

- **SELECT Phase 2 data to be presented at ESMO-IO Annual Congress 2022.** Jounce will present the SELECT data in a poster at ESMO-IO. SELECT is a randomized Phase 2 trial evaluating vopratelimab (vopra), Jounce's inducible T cell costimulator (ICOS) agonist, in combination with pimi versus pimi alone in immunotherapy naïve, TIS^{vopra} biomarker-selected, second line non-small cell lung cancer patients. The poster will update previously announced data on primary and secondary endpoints based on a longer duration of follow up. As previously reported, vopra 0.03 mg/kg in combination with pimi resulted in a 40% response rate and an 80% six month landmark progression-free survival (PFS) by independent central radiology review. These continue to compare favorably to updated results for pimi monotherapy, with a 27.8% response rate and 36% six month landmark PFS, as will be reported at ESMO-IO. Jounce plans to pursue a partnership to enable further development of vopra 0.03 mg/kg in combination with a PD-1 inhibitor.

JTX-1484 (LILRB4/ILT3)

- **Continued advancement of JTX-1484.** JTX-1484 is a monoclonal antibody with an emerging differentiated profile designed to block human LILRB4 (ILT3) expressed on myeloid cells in the tumor microenvironment with the potential to reduce immune suppression and enhance T cell functionality. JTX-1484 is currently in investigational new drug (IND) enabling activities, with the goal of filing an IND application in 2023.
- **JTX-1484 preclinical poster presentation at SITC.** Jounce will be presenting a preclinical poster today on JTX-1484 at this year's annual Society for Immunotherapy of Cancer (SITC) meeting being held from November 9-11 in Boston, MA. The poster will highlight the preclinical evaluation of JTX-1484, an anti-LILRB4 antagonist antibody, for reprogramming of immunosuppressive myeloid cells.



Discovery Pipeline

- **LILRB family preclinical data poster presentation at SITC.** Jounce will present preclinical data in a poster at the SITC annual meeting today on the LILRB family of receptors and the characterization of the expression and function of LILRB receptors on human immune cells in tumor and blood samples across different cancer types.
- **Productive discovery engine.** Jounce continues to advance its growing immuno-oncology pipeline. Its discovery engine is built upon the capability to thoroughly interrogate different cell types in the tumor microenvironment, including T cells and myeloid cells. This approach has resulted in four clinical stage programs, with a fifth in IND enabling studies, over the last 6 years.

Business Update

- **Jounce earns clinical milestone under the CCR8 exclusive license agreement with Gilead Sciences, Inc.** A \$15.0 million clinical milestone payment from Gilead Sciences, Inc. (Gilead) was earned in October 2022, under the exclusive license agreement for GS-1811, an anti-CCR8 antibody for which Gilead has exclusive rights to develop and commercialize. To date, Jounce has earned \$40.0 million of the \$685.0 million in development, regulatory, and commercial milestones possible under the agreement. Additionally, Jounce will be eligible to receive royalties ranging from high single digit to mid-teens based upon on any future worldwide product sales of GS-1811.

Third Quarter 2022 Financial Results:

- **Cash position:** As of September 30, 2022, cash, cash equivalents and investments decreased to \$130.3 million, compared to \$220.2 million as of December 31, 2021. The decrease was due to operating expenses incurred during the period.
- **License and collaboration revenue:** Jounce did not recognize any revenue during the third quarter of 2022 or 2021. The \$15.0 million milestone earned under the Gilead license agreement in October is expected to be received in the fourth quarter of 2022.
- **Research and development expenses:** Research and development expenses were \$23.8 million for the third quarter of 2022, compared to \$23.3 million for the same period in 2021. The increase in R&D expenses was due to increased manufacturing activities and lab supply purchases to support research activities, partially offset by decreased external clinical and regulatory costs for our vopratelimab development program.
- **General and administrative expenses:** General and administrative expenses were \$7.7 million for the third quarter of 2022, compared to \$6.9 million for the same period in 2021. The increase in G&A expense was attributable to increased compensation costs due to increased headcount.
- **Net loss:** Net loss was \$31.0 million for the third quarter of 2022, resulting in basic and diluted net loss per share of \$0.60. Net loss was \$30.1 million for the same period in 2021, resulting in a basic and diluted net loss per share of \$0.59. The increase in net loss is attributable to increased operating expenses in the third quarter of 2022 as compared to 2021.



Financial Guidance:

Based on its current operating and development plans and cost containment efforts, Jounce is reiterating its financial guidance for 2022. Gross cash burn on operating expenses and capital expenditures for the full year 2022 is expected to be at the lower end of the range of \$115.0 million to \$130.0 million. Jounce expects its existing cash, cash equivalents and investments to be sufficient to enable the funding of its operating expenses and capital expenditure requirements into the first quarter of 2024.

Conference Call and Webcast Information:

Jounce Therapeutics will host a live conference call and webcast today at 8:00 a.m. ET. To access the conference call, participants may register [here](#).¹ It is advised to register at least 10 minutes prior to joining the call. The live webcast can be accessed under "Events & Presentations" in the Investors and Media section of the company's website at www.jouncetx.com. The webcast will be archived and made available for replay on the company's website approximately two hours after the call and will be available for 30 days thereafter.

About Jounce Therapeutics:

Jounce Therapeutics, Inc. is a clinical-stage immunotherapy company dedicated to transforming the treatment of cancer by developing therapies that enable the immune system to attack tumors and may provide long-lasting benefits to patients through a biomarker-driven approach. Jounce currently has multiple development stage programs ongoing while simultaneously advancing additional early-stage assets from its robust discovery engine based on its Translational Science Platform. Jounce's highest priority program, JTX-8064, is a LILRB2 (ILT4) receptor antagonist shown to reprogram immune-suppressive tumor associated macrophages to an anti-tumor state in preclinical studies. JTX-8064 is currently being investigated alone and in combination with pimivalimab (formerly JTX-4014), Jounce's internal PD-1 inhibitor, in one monotherapy and eight indication-specific combination therapy cohorts in the Phase 1/2 INNATE trial and is currently enrolling patients with advanced solid tumors in the Phase 2 portion of the study. Jounce's most advanced product candidate, vopratelimab, is a monoclonal antibody that binds to and activates ICOS, and is currently being studied in the SELECT Phase 2 trial. Pimivalimab is a PD-1 inhibitor intended for combination use in the INNATE and SELECT trials and with Jounce's broader pipeline. Additionally, Jounce exclusively licensed worldwide rights to GS-1811 (formerly JTX-1811), a monoclonal antibody targeting CCR8 and designed to selectively deplete T regulatory cells in the tumor microenvironment, to Gilead Sciences, Inc. For more information, please visit www.jouncetx.com.

Cautionary Note Regarding Forward-Looking Statements:

Various statements in this release concerning Jounce's future expectations, plans and prospects, including without limitation, Jounce's expectations regarding financial guidance, gross cash burn, operating expenses, capital expenditures and funding requirements; the timing, initiation or expansion, progress, results of and release of data from clinical trials of Jounce's product candidates, including JTX-8064 and pimivalimab; the timing of an IND filing for JTX-1484; and the presentation of clinical data may constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws and are subject to substantial risks, uncertainties and assumptions. You should not place reliance on these forward-looking statements, which often include words such as, "expect," "goal," "plan," "strive," or similar terms, variations of such terms or the negative of those terms. Although Jounce believes that the expectations reflected in the



forward-looking statements are reasonable, Jounce cannot guarantee such outcomes. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, Jounce's ability to successfully demonstrate the efficacy and safety of its product candidates and future product candidates; risks that the COVID-19 pandemic may disrupt Jounce's business and/or the global healthcare system more severely than anticipated, which may have the effect of delaying enrollment and completion of Jounce's ongoing clinical trials, or delaying timelines or data disclosures and regulatory submissions for its product candidates; the preclinical and clinical results for its product candidates, which may not support further development and marketing approval; the potential advantages of Jounce's product candidates; Jounce's ability to successfully manage its clinical trials; the development plans of its product candidates and any companion or complementary diagnostics; management of Jounce's supply chain for the delivery of drug product and materials for use in clinical trials and research and development activities; actions of regulatory agencies, which may affect the initiation, timing and progress of preclinical studies and clinical trials of Jounce's product candidates; abstract submissions and acceptance, or lack thereof, related to Jounce's clinical and preclinical programs; Jounce's ability to obtain, maintain and protect its intellectual property; Jounce's ability to manage operating expenses and capital expenditures; and those risks more fully discussed in the section entitled "Risk Factors" in Jounce's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission as well as discussions of potential risks, uncertainties, and other important factors in Jounce's subsequent filings with the Securities and Exchange Commission. All such statements speak only as of the date made, and Jounce undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Jounce Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)
(amounts in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
License and collaboration revenue—related party	\$ —	\$ —	\$ —	\$ 26,907
Operating expenses:				
Research and development	23,752	23,288	80,070	65,895
General and administrative	7,653	6,854	22,511	21,786
Total operating expenses	31,405	30,142	102,581	87,681
Operating loss	(31,405)	(30,142)	(102,581)	(60,774)
Other income, net	412	55	721	144
Loss before provision for income taxes	(30,993)	(30,087)	(101,860)	(60,630)
Provision for income taxes	5	6	18	9
Net loss	\$ (30,998)	\$ (30,093)	\$ (101,878)	\$ (60,639)
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.59)	\$ (1.97)	\$ (1.23)
Weighted-average common shares outstanding, basic and diluted	51,694	51,232	51,670	49,488

Jounce Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data (unaudited)
(amounts in thousands)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 130,332	\$ 220,223
Working capital	\$ 118,133	\$ 171,929
Total assets	\$ 158,081	\$ 252,696
Total stockholders' equity	\$ 129,358	\$ 223,805

Investor and Media Contact:

Eric Laub

Jounce Therapeutics, Inc.

+1-857-259-3853

elaub@jouncetx.com

¹ <https://register.vevent.com/register/BI36a5d163e9a3449a8a7140a523628dbf>