

**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 4, 2021**

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 4, 2021, Jounce Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended September 30, 2021. 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 4, 2021
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 4, 2021

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

Jounce Therapeutics Reports Third Quarter 2021 Financial Results

- Commenced enrollment in tumor-specific monotherapy and pimivalimab combination expansion cohorts of INNATE trial of JTX-8064 -

- Ended the quarter with \$249.0 million in cash, cash equivalents and investments -

- Company to host conference call and webcast today at 8:00 AM ET -

CAMBRIDGE, Mass., November 4, 2021 - 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, 2021 and provided a corporate update.

“Jounce has had another very productive quarter as we have made significant progress across all areas of the company and continue to build momentum as we head into the new year. We were pleased to report that we are now actively recruiting patients in the monotherapy and combination therapy expansion portion of the INNATE study, testing JTX-8064 +/- pimivalimab, our own PD-1 inhibitor, in 8 distinct cohorts across 7 tumor types. We also continue to advance patient enrollment in our randomized SELECT study which employs our stringent patient selection strategy and have continued our commitment to build our discovery pipeline,” said Richard Murray, Ph.D., chief executive officer and president of Jounce Therapeutics. “We believe our focus on translational science, biomarker approaches, and targeting new immune mechanisms leads us closer to bringing the right immunotherapies to the right patients.”

Pipeline Update:

JTX-8064 (LILRB2 / ILT4)

- **Completed monotherapy and combination therapy dose escalation 3 week safety review of INNATE:** Jounce has completed the monotherapy and pimivalimab (PD-1 Inhibitor) combination therapy dose escalation 3 week safety review of the Phase 1 trial of JTX-8064, and a preliminary recommended phase 2 dose (RP2D) of 700 mg has been established. To date, JTX-8064 has been well tolerated with no dose limiting toxicities.
- **Enrollment initiated in tumor-specific monotherapy and pimivalimab combination expansion cohorts of INNATE:** Jounce previously announced the initiation of patient enrollment in INNATE tumor-specific expansion cohorts for both JTX-8064 monotherapy and combination therapy of JTX-8064 with pimivalimab in August and October, respectively. The expansion cohorts will study JTX-8064 in three subsets of patients in order to identify the most rapid development paths for JTX-8064 alone or in combination with PD-1 inhibitors:
 - Patients who have progressed on PD-1 inhibitors and are now PD-1 inhibitor resistant,
 - PD-1 inhibitor naïve patients with tumors that do not typically respond to PD-1 inhibitors, and
 - PD-1 inhibitor naïve patients with tumors for which PD-1 inhibitors are approved, but there is still room for improvement.



Vopratelimab (ICOS) and Pimivalimab (PD-1)

- **Continued enrollment in Phase 2 SELECT trial of vopratelimab:** Enrollment continues in SELECT, a randomized Phase 2 trial to evaluate vopratelimab in combination with pimivalimab versus pimivalimab alone in immunotherapy naïve, TIS^{vopra} biomarker-selected, second line non-small cell lung cancer (NSCLC) patients. The SELECT trial also aims to provide additional important single agent data for pimivalimab in a new biomarker selection paradigm. Jounce is on track to report data from the SELECT trial in 2022.

Gilead Sciences begins Phase 1 clinical trial of GS-1811 (formerly JTX-1811)

- The clinical study of GS-1811 (formerly JTX-1811) was initiated by Gilead Sciences. GS-1811, which Jounce discovered and progressed through to IND, is out licensed to Gilead and is the fourth internally developed candidate to enter the clinic.

Corporate Update:

Jigar Raythatha Appointed to the Board of Directors

- On September 15th, 2021, Jounce announced the appointment of former chief executive officer of Constellation Pharmaceuticals and former Jounce chief business officer, Jigar Raythatha, to its board of directors.

Third Quarter 2021 Financial Results:

- **Cash position:** As of September 30, 2021, cash, cash equivalents and investments were \$249.0 million, compared to \$213.2 million as of December 31, 2020. The increase was primarily due to receipt of \$90.9 million in net proceeds from the follow-on public offering and sales under Jounce's at-the-market ("ATM") offering program completed first quarter of 2021 and receipt of a \$25.0 million milestone from Gilead in the third quarter of 2021, offset by operating expenses incurred.
- **License and collaboration revenue:** No license or collaboration revenue was recognized in the third quarter of 2021 or 2020.
- **Research and development expenses:** Research and development expenses were \$23.3 million for the third quarter of 2021, compared to \$18.0 million for the same period in 2020. The increase in research and development expenses was primarily due to increased clinical and regulatory costs for INNATE and SELECT, increased manufacturing activities performed for Jounce's development programs and payroll and stock-based compensation expense.
- **General and administrative expenses:** General and administrative expenses were \$6.9 million for the third quarter of 2021, compared to \$7.1 million for the same period in 2020. The decrease in general and administrative expenses was primarily due to decreased professional fees offset by increases in other administrative costs.
- **Net loss:** Net loss was \$30.1 million for the third quarter of 2021, resulting in basic and diluted net loss per share of \$0.59. Net loss was \$24.9 million for the same period in 2020, resulting in a basic and diluted net loss per share of \$0.73. The increase in net loss is attributable to increased operating expenses, the decrease in the net loss per share is attributable to increased number of shares outstanding as compared to the same period in 2020.



Financial Guidance:

Based on its current operating and development plans, Jounce is narrowing its financial guidance on gross cash burn on operating expenses and capital expenditures for the full year 2021 to \$100.0 million to \$110.0 million. Jounce expects to end fiscal year 2021 with approximately \$220.0 million in cash, cash equivalents and investments.

Given the strength of its balance sheet, Jounce continues to expect its existing cash, cash equivalents and investments to be sufficient to enable the funding of its operating expenses and capital expenditure requirements through the third quarter of 2023.

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, please dial (866) 916-3380 (domestic) or (210) 874-7772 (international) and refer to conference ID 6873343. The live webcast can be accessed under "Events & Presentations" in the Investors and Media section of Jounce's website at www.jouncetx.com. The webcast will be archived and made available for replay on Jounce's website approximately two hours after the call and will be available for 30 days.

About JTX-8064

JTX-8064 is a humanized IgG4 monoclonal antibody designed to specifically bind to Leukocyte Immunoglobulin Like Receptor B2 (LILRB2/ILT4) and block interactions with its ligands. JTX-8064 is the first tumor-associated macrophage candidate developed from Jounce's Translational Science Platform. Preclinical data presented at the 2020 Society for Immunotherapy of Cancer's Annual Meeting and the 2019 and 2021 American Association for Cancer Research Annual Meetings support the development of JTX-8064 as a novel immunotherapy to reprogram immune-suppressive macrophages and enhance anti-tumor immunity. A Phase 1 clinical trial named INNATE (NCT04669899) of JTX-8064 as a monotherapy and in combination with Jounce's internal anti-PD-1 inhibitor, pimivalimab (formerly JTX-4014) is currently enrolling patients with advanced solid tumors into tumor-specific expansion cohorts.

About Pimivalimab

Pimivalimab (formerly JTX-4014) is a well-characterized fully human IgG4 monoclonal antibody designed to block binding to PD-L1 and PD-L2. Pimivalimab demonstrated a 17% durable overall response rate in a Phase 1 trial of 18 heavily pre-treated PD-(L)1 inhibitor naïve patients, which excluded all tumor types for which PD-(L)1 inhibitors were approved. In this Phase 1 trial, pimivalimab was shown to have an acceptable safety profile. Pimivalimab is currently being assessed in the INNATE Phase 1 trial (NCT04669899) in combination with JTX-8064, a LILRB2 (ILT4) inhibitor. Pimivalimab is also being assessed in the SELECT Phase 2 clinical trial (NCT04549025) in combination with vopratelimab, a clinical-stage monoclonal antibody that binds to and activates ICOS, the Inducible T cell CO-Stimulator, a protein on the surface of certain T cells commonly found in many solid tumors.



About Vopratelimab

Vopratelimab is a clinical-stage monoclonal antibody that binds to and activates ICOS, the Inducible T cell CO-Stimulator, a protein on the surface of certain T cells commonly found in many solid tumors. Vopratelimab is currently being assessed in the SELECT Phase 2 clinical trial (NCT04549025) in combination with Jounce's internal investigational PD-1 inhibitor, pimivalimab (formerly JTX-4014), compared to pimivalimab alone. The SELECT trial is currently enrolling approximately 75 immunotherapy naïve NSCLC patients who have been pre-selected with the TIS^{vopra} predictive biomarker, an 18 gene RNA tumor inflammation signature which predicted the emergence of ICOS hi CD4 T cells and clinical benefit in the ICONIC trial of vopratelimab alone and in combination with a PD-1 inhibitor. SELECT is powered to demonstrate the statistical superiority of the combination of vopratelimab plus pimivalimab compared to pimivalimab.

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 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. 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, operating expenses and capital expenditures; the timing, initiation, progress, results of and release of data for clinical trials of Jounce’s product candidates, including JTX-8064, vopratelimab and pimivalimab; identification, selection and enrollment of patients for Jounce’s clinical trials 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 “on track,” “aim,” “plan,” “expect” 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, 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; Jounce’s ability to successfully demonstrate the efficacy and safety of its product candidates and future 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; 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,	
	2021	2020	2021	2020
Revenue:				
License and collaboration revenue—related party	\$ —	\$ —	\$ 26,907	\$ —
Operating expenses:				
Research and development	23,288	18,002	65,895	58,671
General and administrative	6,854	7,102	21,786	21,867
Total operating expenses	30,142	25,104	87,681	80,538
Operating loss	(30,142)	(25,104)	(60,774)	(80,538)
Other income, net	55	203	144	1,238
Loss before provision for income taxes	(30,087)	(24,901)	(60,630)	(79,300)
Provision for income taxes	6	2	9	14
Net loss	\$ (30,093)	\$ (24,903)	\$ (60,639)	\$ (79,314)
Net loss per share, basic and diluted	\$ (0.59)	\$ (0.73)	\$ (1.23)	\$ (2.33)
Weighted-average common shares outstanding, basic and diluted	51,232	34,159	49,488	34,081

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 249,038	\$ 213,188
Working capital	\$ 211,148	\$ 192,067
Total assets	\$ 280,385	\$ 244,236
Total stockholders' equity	\$ 251,367	\$ 211,294

Investor and Media Contact:

Eric Laub
+1-857-259-3853
elaub@jouncetx.com

Mark Yore
+1-857-200-1255
myore@jouncetx.com