

**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 5, 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 August 5, 2021, Jounce Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended June 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 August 5, 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: August 5, 2021

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

Jounce Therapeutics Reports Second Quarter 2021 Financial Results

- *INNATE monotherapy dose escalation enrollment completed and target dose selected, on track to initiate indication specific expansions in third quarter 2021-*
- *Announced two additional LILRB family targets as potential future development candidates -*
- *Ended the quarter with \$246.1 million in cash, cash equivalents and investments -*
- *Company to host conference call and webcast today at 8:00 AM ET -*

CAMBRIDGE, Mass., August 5, 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 second quarter ended June 30, 2021 and provided a corporate update.

“I am very pleased with the progress Jounce has made this quarter as we continued to advance our two proof of concept studies, INNATE and SELECT, achieved IND clearance on our fourth internally discovered program and expanded our discovery programs to include additional LILRB family members. Our team has made important and rapid progress in our INNATE study with the announcement today of monotherapy dose escalation enrollment completion and target dose selection. We look forward to beginning the next stages of the trial in third quarter of this year,” said Richard Murray, Ph.D., chief executive officer and president of Jounce Therapeutics. “We remain steadfast in our commitment to discover and develop novel IO therapies to meet the growing unmet medical need experienced in cancer patients, particularly in the area of PD-(L)1 inhibitor resistance. 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 enrollment in monotherapy dose escalation portion of INNATE:** Jounce announces today that the monotherapy dose escalation portion of the Phase 1 trial of JTX-8064 is complete. The monotherapy dose escalation included seven doses ranging from 50 mg to the highest planned dose of 1200 mg. To date, JTX-8064 has been well-tolerated with no dose limiting toxicities.

- **Identified target dose for next stages of INNATE:** Jounce announces today the selection of its target dose of 700 mg. The selected target dose was based on a combination of safety, pharmacokinetic, and receptor occupancy data in the first three-week cycle. During the third quarter of 2021, Jounce expects to open eight expansion cohorts for enrollment, one with JTX-8064 monotherapy at its target dose and seven with JTX-8064 in combination with pimivalimab.
- **Presented trial in progress posters at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting:** In June 2021, Jounce presented a trial in progress poster at the ASCO Annual Meeting on INNATE. The poster included the study design and the rationale for indications chosen for the expansion cohorts.

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.
- **Presented trial in progress poster at the ASCO 2021 Annual Meeting:** In June 2021, Jounce presented a trial in progress poster at the ASCO Annual Meeting on SELECT. The poster described the study design, TIS^{vopra} biomarker, and patient selection strategy of the SELECT trial.

JTX-1811 (CCR8)

- **Clearance of IND triggering first milestone under Gilead license agreement:** In June 2021, Jounce received clearance from the U.S. Food and Drug Administration (FDA) of an investigational new drug (IND) application for JTX-1811, a potential first-in-class antibody designed to bind to CCR8 and selectively deplete immunosuppressive tumor-infiltrating T regulatory cells. The IND clearance triggered a \$25.0 million milestone payment to Jounce which was received in July 2021. Gilead now has sole rights to develop and commercialize the JTX-1811 program, which will be referred to as GS-1811 in their pipeline.

Discovery Pipeline

- **Announced new discovery program targets:** Jounce continues to invest in and advance its growing immuno-oncology pipeline. The broad discovery pipeline includes multiple programs targeting diverse immune cell types and PD-(L)1 inhibitor resistance mechanisms. Jounce is rapidly advancing two additional LILRB family programs through discovery, one targeting LILRB1 and the other targeting LILRB4. With the goal of submitting a new IND every 12 to 18 months, Jounce expects at least one of its next development candidates to target the LILRB family of receptors.



Second Quarter 2021 Financial Results:

- **Cash position:** As of June 30, 2021, cash, cash equivalents and investments were \$246.1 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 offering program completed during the period, offset by operating expenses incurred. This amount excludes the \$25.0 million milestone Jounce received from Gilead in July 2021.
- **License and collaboration revenue:** Jounce recognized \$25.4 million of license and collaboration revenue during the second quarter of 2021. License and collaboration revenue recognized during the period was related to milestone achievement and research and transition services performed under the license agreement with Gilead. No revenue was recognized for the same period in 2020.
- **Research and development expenses:** Research and development expenses were \$22.1 million for the second quarter of 2021, compared to \$21.0 million for the same period in 2020. The increase in research and development expenses was primarily due to increased manufacturing activities performed for Jounce's development programs and increased clinical and regulatory spend on JTX-8064 offset by decreased spend on vopratelimab.
- **General and administrative expenses:** General and administrative expenses were \$7.3 million for the second quarter of 2021, compared to \$7.2 million for the same period in 2020. The increase in general and administrative expenses was primarily due to increased insurance expense.
- **Net loss:** Net loss was \$4.0 million for the second quarter of 2021, resulting in basic and diluted net loss per share of \$0.08. Net loss was \$28.0 million for the same period in 2020, resulting in a basic and diluted net loss per share of \$0.82. The decrease in net loss and net loss per share was attributable to revenue recognized in the second quarter of 2021.

Financial Guidance:

Based on its current operating and development plans, Jounce continues to expect gross cash burn on operating expenses and capital expenditures for the full year 2021 to be approximately \$95.0 million to \$110.0 million.

Given the strength of its balance sheet, Jounce expects 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 4291658. 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 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. A Phase 1 clinical trial, named INNATE, of JTX-8064 as a monotherapy and in combination with pimivalimab (formerly JTX-4014), Jounce's internal PD-1 inhibitor, is currently enrolling patients with advanced solid tumors. 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 obtained IND clearance for and exclusively licensed worldwide rights to 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; the timing of IND filings; and the timing, progress and results of preclinical studies for Jounce’s product candidates, including JTX-1811, and any future product candidates 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 “aim,” “goal,” “expect,” “plan,” “on track,” “will” 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License and collaboration revenue—related party	\$ 25,368	\$ —	\$ 26,907	\$ —
Operating expenses:				
Research and development	22,100	21,023	42,607	40,669
General and administrative	7,317	7,226	14,932	14,765
Total operating expenses	29,417	28,249	57,539	55,434
Operating loss	(4,049)	(28,249)	(30,632)	(55,434)
Other income, net	40	285	89	1,035
Loss before provision for income taxes	(4,009)	(27,964)	(30,543)	(54,399)
Provision for income taxes	2	4	3	12
Net loss	\$ (4,011)	\$ (27,968)	\$ (30,546)	\$ (54,411)
Net loss per share, basic and diluted	\$ (0.08)	\$ (0.82)	\$ (0.63)	\$ (1.60)
Weighted-average common shares outstanding, basic and diluted	51,212	34,053	48,601	34,041

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 246,148	\$ 213,188
Working capital	\$ 241,278	\$ 192,067
Total assets	\$ 306,160	\$ 244,236
Total stockholders' equity	\$ 278,462	\$ 211,294

Investor and Media Contact:

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