

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): December 11, 2020**

**OPIANT PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation)

**001-38193**

(Commission File Number)

**46-4744124**

(IRS Employer Identification No.)

**233 Wilshire Blvd. Suite 280  
Santa Monica, CA**

(Address of Principal Executive Offices)

**90401**

(Zip Code)

**(310) 598 5410**

Registrant's telephone number, including area code

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, par value \$0.001 per share	OPNT	Nasdaq Stock Market LLC

**Item 1.01 Entry into a Material Definitive Agreement.**

On September 19, 2018, Opiant Pharmaceuticals, Inc. (the “**Company**”) entered into a contract (“**Contract**”) with the Biomedical Advanced Research and Development Authority (“**BARDA**”), which is part of the U.S. Health and Human Services Office of the Assistant Secretary for Preparedness and Response, to accelerate the Company’s development of OPTN003, its lead product candidate. OPTN003, nasal nalmefene, is a potent, long-acting opioid antagonist currently in development for the treatment of opioid overdose.

On December 14, 2020, the Company announced a modification to the Contract (the “**Modification**”), which provides an additional commitment from BARDA of up to \$3.5 million to advance the clinical development of OPNT003. The Modification increases the total potential value of the Contract to \$8.1 million.

A copy of the Modification is attached to this Current Report on Form 8-K as Exhibit 10.1 and is incorporated herein by reference. The description of the Modification provided herein is qualified in its entirety by reference to the terms of the Contract as set forth in Exhibit 10.1.

**Item 8.01 Other Events**

On December 14, 2020, the Company issued a press release announcing the Modification. A copy of the press release is filed herewith as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No. Description

10.1 [Amendment of Solicitation/Modification of Contract](#)

99.1 [Press Release of Opiant Pharmaceuticals, Inc., dated December 14, 2020](#)

**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.

**OPIANT PHARMACEUTICALS, INC.**

Dated: December 14, 2020

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES	
2. AMENDMENT/MODIFICATION NO. P00005		4. REQUISITION/PURCHASE REQ. NO. OS269653	5. PROJECT NO. (If applicable) 1 8	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201	CODE ASPR-BARDA	
8. NAME AND ADDRESS OF CONTRACTOR (No. street, county, State and ZIP Code) OPIANT PHARMACEUTICALS, INC 1530943 Attn: David O'Toole OPIANT PHARMACEUTICALS, INC. 201 SANTA MONICA BLVD STE 500 SANTA MONICA CA 904012213		(X) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)	
CODE 1530943 FACILITY CODE		X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHS0100201800029C	10B. DATED (SEE ITEM 13) 09/19/2018	
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended. <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By complying with items 8 and 15, and returning _____ copies of the amendment. (b) By acknowledging receipt of this amendment on each copy of the offer submitted, or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required) 2021.1992021.25106		Net Increase:		\$3,500,000.00
13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.			
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14 PURSUANT TO THE AUTHORITY OF FAR 43.103(b).			
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF FAR 52.243-3 - CHANGES - COST REIMBURSEMENT - ALTERNATE V			
	D. OTHER (Specify type of modification and authority)			
E. IMPORTANT: Contractor <input type="checkbox"/> is not <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Tax ID Number: 46-4744124 DUNS Number: 079253495 The purpose of this modification is to modify (1) Articles B.2 Base Period; B.3 Option Prices; B.4 Limitations Applicable to Direct Costs; C.1. Statement of Work; F.1. Period of Performance; G.1. Contracting Officer; G.2. Contracting Officer's Representative (COR); and Section J List of Attachments, Attachment #1. In addition, this modification will provide supplemental funding in support of performance related to Option One (1).  The contract current value is increased by \$3,500,000.00 from \$2,971,230.00 to \$6,471,230.  The contract obligated amount is increased by \$3,500,000.00 from \$2,971,230.00 to Continued ...  Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect				
15A. NAME AND TITLE OF SIGNER (Type or print) PHIL SKOLNICK, CSO		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) ROSHAWN K. MAJORS		16C. DATE SIGNED
15B. CONTRACTOR/OFFEROR Phil Skolnick (Signature of person authorized to sign)		15C. DATE SIGNED 12/11/20		16B. UNITED STATES OF AMERICA RoShawn Washington (Simpson) (Signature of Contracting Officer)
Previous edition unusable		STANDARD FORM 30 (REV. 11/2016) Prescribed by GSA FAR (48 CFR) 53.243		

**CONTINUATION SHEET**

REFERENCE NO. OF DOCUMENT BEING CONTINUED  
HHSO100201800029C/P00005

PAGE OF  
Exhibit 10.1 | 8

NAME OF OFFEROR OR CONTRACTOR  
OPIANT PHARMACEUTICALS, INC 1530943

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>\$6,471,230.00.</p> <p>The contract overall value is increased by \$3,500,000.00 from \$4,590,280.00 to \$8,090,280.00.</p> <p>The period of performance end date for the Base period is December 20, 2021. UNCHANGED</p> <p>The period of performance end date for Option One (1) is December 20, 2021. UNCHANGED Appr. Yr.: 2021 CAN: 1992021 Object Class: 25106 Period of Performance: 09/19/2018 to 12/20/2021</p> <p>Add Item 5 as follows:</p>				
5	<p>ASPR-21-00287 -- Supplemental funding for Option 1 to Opiant Pharmaceuticals for the development of Intranasal Nalmafene under contract HHSO100201800029C Obligated Amount: \$3,500,000.00</p> <p>All other terms and conditions remain UNCHANGED.</p> <p><b><u>Additional Pages "Intentionally Omitted".</u></b></p>				3,500,000.00



## **Opiant Pharmaceuticals Announces Additional \$3.5 million Funding Under BARDA Contract for OPNT003 Nasal Nalmefene Development Program**

**SANTA MONICA, Calif., December 14, 2020** -- Opiant Pharmaceuticals, Inc. ("Opiant") (NASDAQ: OPNT) today announced an additional commitment of up to \$3.5 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, to advance the clinical development of OPNT003, nasal nalmefene, for opioid overdose. The contract modification increases the total potential value of the BARDA contract to \$8.1 million.

"We thank BARDA for their ongoing support of OPNT003, nasal nalmefene," said Roger Crystal, M.D., President and Chief Executive Officer of Opiant. "We believe OPNT003, nasal nalmefene, has the potential to be a best-in-class rescue agent for preventing opioid overdose deaths, particularly from synthetic opioids like fentanyl. We remain on track to file a New Drug Application with the U.S. Food and Drug Administration by the end of 2021."

An earlier award from BARDA for up to \$4.6 million, combined with a \$7.4 million grant Opiant received from the National Institute on Drug Abuse ("NIDA"), also supports the clinical development and U.S. regulatory submission of OPNT003. The additional BARDA support will fund both a planned pharmacodynamic study in healthy volunteers and development work associated with the use of Aptar Pharma's Unit Dose System.

Opioid overdose is a significant public health crisis that has been exacerbated by the increased availability and abuse of synthetic opioids, such as fentanyl. Fentanyl is 50-fold more potent than heroin, far easier and less expensive to produce, and has a significantly longer half-life. Fentanyl and related synthetic opioids were linked to more than 75% of the nearly 51,000 opioid overdose deaths in 2019 in the U.S. The contract with BARDA allows for development of OPNT003 as a medical countermeasure in a chemical attack using synthetic opioids.

This project has been supported in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800029C.

### **About OPNT003**

OPNT003, nasal nalmefene, is in development as a potent, rapid-onset, long-acting opioid antagonist for the treatment of opioid overdose. OPNT003 is designed as a rescue medication that could be especially useful in treating overdose by high-potency synthetic opioids, such as fentanyl. OPNT003 is also being considered as an antidote in a civilian mass casualty event. The development of OPNT003 is supported by grants from the NIH and BARDA. Opiant intends to pursue a 505(b)(2) regulatory pathway for OPNT003.

### **About Opiant Pharmaceuticals, Inc.**

Opiant Pharmaceuticals, Inc., the company that developed NARCAN® Nasal Spray, is building a leading franchise of new medicines to combat addictions and drug overdose.

For more information visit: [www.opiant.com](http://www.opiant.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forward-looking statements, and among other things, our ability to maintain cash balances and successfully commercialize or partner our product candidates currently under development. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors. Additional factors that could materially affect actual results can be found in our Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 4, 2020, including under the caption titled "Risk Factors." These and other factors may cause our actual results to differ materially from any forward-looking statement. We undertake no obligation to update any of the forward-looking statements after the date of this press release to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

For Media and Investor Inquiries:

Ben Atkins, Opiant

(310) 598-5410

[batkins@opiant.com](mailto:batkins@opiant.com)