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 16, 2020

Pandion Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39381**	**83-3015614**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

134 Coolidge Avenue **Watertown, Massachusetts** **(Address of Principal Executive Offices)**	**02472** **(Zip Code)**

Registrant's telephone number, including area code: (617) 393-5925

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:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**PAND**	**Nasdaq Global Select Market**

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 16, 2020, Pandion Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2020. The full text of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, 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

The following exhibit is furnished herewith:

99.1 Press Release issued by the Company on November 16, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PANDION THERAPEUTICS, INC.

Date: November 16, 2020

By: /s/ Rahul Kakkar
Name: Rahul Kakkar
Title: Chief Executive Officer

Pandion Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Update

- Enrollment and dosing complete in Phase 1a clinical trial of PT101; top-line results expected early 2021
- PT627 systemic PD-1 agonist development candidate nominated; IND-enabling studies expected to initiate 4Q 2020
- Presented preclinical data at FOCIS 2020 highlighting potential of TALON platform in autoimmune disease

WATERTOWN, Mass. – November 16, 2020 - Pandion Therapeutics, Inc. (Nasdaq: PAND), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, today reported financial results for the three and nine months ended September 30, 2020, and provided a recent business update.

“The third quarter was marked by our entrance into the public markets. With the additional proceeds from our IPO, we are well-capitalized to advance our pipeline of engineered proteins that act to restore immune system balance in autoimmunity,” said Rahul Kakkar, M.D., Chief Executive Officer of Pandion Therapeutics. “We’ve made substantial progress in our Phase 1a clinical trial for our lead program, PT101, and now that enrollment and dosing of all cohorts are complete, we expect to announce top-line results in early 2021. In this Phase 1a clinical trial, we are seeking to evaluate the safety and tolerability of PT101 and to demonstrate PT101’s selectivity for activating regulatory T cells, without activating conventional T cells or NK cells. We believe selective expansion of regulatory T cells is important to maximize clinical benefit for patients within this drug class.”

Dr. Kakkar continued, “Following PT101, is our PD-1 agonism program franchise. PD-1 is another control node of the immune system, and we believe activation of PD-1 could help to treat various autoimmune diseases. Work continues on our PD-1 agonists. We plan to initiate investigational new drug (IND)-enabling studies with our systemic PD-1 agonist, PT627, in the fourth quarter of this year and are on-track to enter IND-enabling preclinical studies for our GI/liver-tethered PD-1 agonist, PT001, in the first half of 2021. We are proud of the progress made on each of these molecules as highlighted in our abstracts presented at FOCIS in October of this year.”

Third Quarter & Recent Business Updates

- **Completed enrollment in Phase 1a clinical trial of PT101.** PT101 is an IL-2 mutein designed to be selective for activation of regulatory T cells, which have the potential to reestablish control of the immune system response in patients with autoimmune disease. The Company completed enrollment and dosing of its Phase 1a double-blind, placebo controlled clinical trial testing the safety and tolerability of single ascending doses of PT101 in healthy volunteers in October 2020.

- **Expect top-line results from the Phase 1a clinical trial of PT101 in early 2021.** In addition to safety and tolerability data, the trial is also assessing PT101's intended mechanism of action. Top-line data are expected to provide information on:
    - *Expansion of regulatory T cells (Tregs) and durability of this expansion.* Academic literature suggests a two-fold expansion of total Tregs can lead to clinical benefit for autoimmune diseases.
    - *Selectivity of PT101 for Tregs over immune-activating conventional T cells (Tconv) and natural killer (NK) T cells*. Academic literature associates Tconv and NK cell expansion with loss of clinical benefit and increased risk of adverse events, suggesting selectivity for regulatory T cell expansion may be critical to achieve clinical benefit.
- **Nominated PT627 as the Company's systemic PD-1 agonist development candidate and plan to initiate IND-enabling preclinical studies in 4Q2020. GI/Liver-tethered PD-1 agonist on-track to enter IND-enabling studies 1H 2021.** PD-1 is an inhibitory receptor-control node present on activated conventional T cells. By activating the PD-1 receptor, our PD-1 agonist antibodies have the potential to attenuate effector T cell responses, and may have potential for the treatment of autoimmune diseases. Pandion is developing both a systemic PD-1 agonist antibody and a GI/liver-tethered PD-1 agonist bifunctional antibody.
- **Presented research highlighting potential of Pandion's modular pipeline in autoimmune diseases at FOCIS and the European Antibody Congress.** The Company's drug design and discovery platform allows for the combination of a specific tissue tether with an immune effector molecule within the same bifunctional antibody. Pandion highlighted that two of its tissue tethers, skin and gut, in combination with various effectors demonstrated promising results in animal models of vitiligo and graft vs. host disease, respectively.
- **Completed Initial Public Offering (IPO), raising approximately $153 million in gross proceeds in July 2020.**

Financial Results for Third Quarter of 2020

- **Cash Position:** Cash and cash equivalents were $232.3 million as of September 30, 2020, as compared to $16.0 million as of December 31, 2019. The cash balance includes the proceeds from the Company's IPO in July 2020. The Company expects that its existing cash and cash equivalents will be sufficient to fund its operations through the first half of 2024.
- **Research and Development (R&D) Expenses:** R&D expenses were $9.3 million for the quarter ended September 30, 2020, compared to $4.4 million for the quarter ended September 30, 2019. The increase was primarily due to higher consulting services and development activities outsourced to Contract Research Organizations.
- **General and Administrative (G&A) Expenses:** G&A expenses were $4.3 million for the quarter ended September 30, 2020, compared to $1.5 million for the quarter ended September 30, 2019. The increase was primarily due to an increase in professional services, personnel-related costs, including increase in non-cash equity-based compensation, and additional insurance premiums associated with being a public company.
- **Net Loss:** Net loss attributable to common stockholders was $11.9 million, or a net loss of $0.51 per basic and diluted share, for the quarter ended September 30, 2020, compared to $6.9 million, or a net loss of $6.72 per basic and diluted share, for the quarter ended September 30, 2019.

About Pandion Therapeutics

Pandion Therapeutics is developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Pandion's TALON (Therapeutic Autoimmune reguLatOry proteiN) drug design and discovery platform enables the company to create a pipeline of product candidates using immunomodulatory effector modules, with the ability to also combine an effector module with a tissue-targeted tether module in a bifunctional format. Pandion's lead product candidate PT101, a combination

of an interleukin-2 mutein effector module with a protein backbone, is designed to selectively expand regulatory T cells systemically, without activating proinflammatory cells, such as conventional T cells and natural killer cells, is currently in a Phase 1a clinical trial. Pandion is continuing to develop and expand its library of effector and tether modules as part of its earlier-stage research and discovery pipeline. For more information, please visit www.pandiontx.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company’s strategy and clinical development plans, timelines and prospects, the timing of availability of clinical trial data and the Company’s ability to fund its operations through the first half of 2024, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Pandion’s ability to obtain and maintain necessary approvals from the FDA and other regulatory authorities; initiate preclinical studies and clinical trials of PT101, PT627, PT001 and its other product candidates; advance PT101, PT627, PT001 and its other product candidates in preclinical research and clinical trials; replicate in clinical trials positive results found in preclinical studies; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties and other important factors, in the Company’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ 2,632	$ —	$ 6,588	$ —
Operating Expenses				
Research and development	9,286	4,386	25,088	14,405
General and administrative	4,336	1,522	8,200	3,136
Total operating expenses	13,622	5,908	33,288	17,541
Loss from operations	(10,990)	(5,908)	(26,700)	(17,541)
Interest income	9	63	54	207
Interest expense	(251)	—	(333)	—
Fair value adjustments to convertible note	—	—	89	—
Net Loss	(11,232)	(5,845)	(26,890)	(17,334)
Change in redemption value of redeemable convertible preferred shares	(664)	(1,027)	(4,909)	(2,963)
Net loss attributable to common shareholders	(11,896)	(6,872)	(31,799)	(20,297)
Net loss per common share, basic and diluted	$ (0.51)	$ (6.72)	$ (3.71)	$ (19.91)
Weighted-average number of shares outstanding used in computing net loss per common share, basic and diluted	23,274,944	1,022,464	8,582,039	1,019,673

Condensed Balance Sheet Data
(in thousands)

	September 30 2020 (unaudited)	December 31, 2019
Cash and cash equivalents	$ 232,324	$ 15,970
Total assets	240,955	21,019
Total liabilities	16,120	16,841
Total stockholders'/members' equity(deficit)	224,835	(42,789)

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