UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

August 30, 2021

Albert DaCosta
Chief Executive Officer
Paragon 28, Inc.
14445 Grasslands Drive
Englewood, CO 80112

Re: Paragon 28, Inc.
Draft Registration Statement on Form S-1
Submitted August 2, 2021
CIK No. 0001531978

Dear Mr. DaCosta:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Market and Industry Data, page i

1. We note your statement cautioning investors not to place undue reliance on market share data included in the prospectus. Such statement may imply an inappropriate disclaimer of responsibility with respect to the third party information; therefore, please either remove the disclaiming language or clearly state in this section that you are liable for all information in the prospectus.

Overview, page 1

2. We note your disclosure on page 52 that most of your currently marketed products are either Class II medical devices cleared by the FDA or Class I medical devices exempt for general orthopaedic use. Please revise to include disclosure of the Class I and II classifications in the Summary as well, particularly for your flagship products. Please also discuss whether any of your products are classified as Class III medical devices.

3. We refer to your disclosure on pages 44 and 45 that you have obtained clearance for most of your products in the United States through the 510(k) clearance process. Please revise to explain when you commenced work designing the flagship products discussed in the prospectus and when your products received 510(k) clearance. Please also include a description of the patient population and indications for key products for which you have received FDA 510(k) clearance.

Summary Risk Factors, page 5

4. Please disclose as a principal risk factor the risk of substantial dilution as discussed on page 64. Also when discussing the risk of dilution in the risk factors section, please discuss the effect that the redeemable convertible preferred stock may have upon dilution.

Use of Proceeds, page 75

5. To the extent known, please revise to disclose the approximate amount of proceeds you intend to allocate toward each of the purposes identified in this section. We also note your disclosure on page 20 that you have focused on specific research programs and products for target indications due to limited financial resources and in the Summary that you have 30 products in the development pipeline, the majority of which will be launched commercially in the next 24 months. Please confirm whether you intend to use the proceeds of the offering towards the development of any specific programs or products, and if so, how much you intend to allocate and how far the proceeds from the offering will allow you to proceed with such programs, as applicable. Refer to Instruction 3 to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Estimates
Stock-Based Compensation, page 95

6. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business, page 98

7. Please clarify the meaning of scientific or technical terms the first time they are used in the Business section or in close proximity thereto in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by calcaneus, arthroplasty, navicular fracture pattern, MTP fusion, TAR procedure, cannulated and laser sintering technology.

Our Growth Strategy, page 104

8. We note your disclosure on page 105 that you recently signed a licensing agreement with ConforMIS to add patient specific instruments to the company's portfolio. To the extent material, please disclose the material terms of the agreement and file the agreement as an exhibit. See Item 601(b)(10) of Regulation S-K for guidance.

Our Solutions, page 110

9. We refer to your disclosure on page 127 and elsewhere in the prospectus that you have developed a broad set of published studies and that the safety and clinical performance of your products are supported by more than 48 published clinical whitepapers or studies. Please revise your disclosure in this section and elsewhere to disclose, if true, whether you funded or sponsored the clinical studies and if your employees were involved in both the studies and publications.

10. We note your reliance of several published studies disclosed on pages 114, 121 and 123 relating to your Gorilla Plating System and PROMO Correction System. Please revise to clarify the scope and design of the studies, whether the studies were powered for statistical significance, whether any adverse events were observed, and to discuss the data from the results to support the conclusions drawn.

11. Please expand your disclosure on page 116 of the bench studies you conducted to support your 510(k) submission to the FDA for your screw systems.

12. We refer to your disclosure on page 119 relating to a clinical study of your Patient Specific Talus Spacer. Please revise your characterization of the clinical study to discuss the data supporting the disclosed conclusions. For example, please discuss the design and scope and the primary endpoint, the statistical significance of the results and whether any adverse events were observed.

Product Development and Pipeline, page 126

13. We refer to your disclosure on page 126 relating to your collaboration with the University of Michigan and Colorado State University. Please expand your disclosure to include a brief description of the material terms of such collaborations, including whether you are funding any studies and research and if any compensation was involved.

Intellectual Property, page 128

14. We note your disclosure on pages 128 and 129 relating to your patent portfolio in the U.S. and in foreign jurisdictions. Please clarify your disclosure to identify for each patent family (including the three in-licensed patents), the scope and technology of each such patent family or patent application, the type of patent protection (such as composition of matter, use or process), jurisdiction and expiration years. Consider adding tabular disclosure in addition to the narrative for ease of use.

15. You disclose on page 128 that your patent portfolio includes three in-licensed patents. We also note your disclosure on pages 105 and 168 in the Business section relating to your license agreements with ConforMIS and Biedermann Technologies GmbH. Please include disclosure in this section identifying the third parties from whom you license intellectual property, the scope of such agreements and the technology and products to which such patent rights relate.

Manufacturing and Supply, page 129

16. We note your risk factor disclosure on page 25 that for certain critical components used in your products, you rely on single source manufacturers and suppliers. Please expand your disclosure to discuss your sources, the availability of raw materials and the names of any principal suppliers and manufacturers. See Item 101(h)(4)(v) of Regulation S-K.

Principal Stockholders, page 165

17. In your revised prospectus, please include in the footnotes to your table to identify the natural persons who are the beneficial owners of the shares held by Bird-B, AG and entities affiliated with MVM.

Certain Relationships and Related Party Transactions
Biedermann License Agreement, page 168

18. We note your disclosure regarding the above referenced agreement. Please file the agreement as an exhibit to the registration statement, or provide your analysis supporting your conclusion that filing is not required. See Item 601(b)(10) of Regulation S-K for guidance.

Consolidated Financial Statements
Notes to Consolidated Financial Statements
Note 2. Summary of Significant Accounting Policies
Intangibles, page F-10

19. Please tell us and revise future filings to disclose the nature of the capitalized patent costs and the basis for capitalization. Please refer to FASB ASC 350-30- 25-3.

Revenue Recognition, page F-11

20. You disclose several different types of revenue streams such as sale of implants, disposables and surgical instrumentation. Please expand your revenue recognition disclosures to provide disaggregated revenue disclosures pursuant to ASC 606-10-50-5 or tell us and explain in your document why additional disclosure is not required. Please refer to the guidance in paragraphs 606-10-55-89 through 55-91.

General

21. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Ibolya Ignat at 202-551-3636 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Phillip Stoup, Esq.