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): February 27, 2024

ABSCI CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**001-40646**	**85-3383487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

18105 SE Mill Plain Blvd
Vancouver, WA 98683
(Address of principal executive offices, including zip code)

(360) 949-1041
(Registrant's telephone number, including area code)

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:

☐ 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, $0.0001 par value per share	ABSI	The 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 February 27, 2024, Absci Corporation (the "Company", "we", "our"), disclosed preliminary unaudited financial highlights for the three months and year ended December, 31, 2023. Based upon preliminary estimates and information available to the Company as of the date of this Current Report on Form 8-K:

- As of December 31, 2023, we had approximately $97.7 million in unrestricted cash and cash equivalents and short-term investments.
- For the three months and year ended December 31, 2023, we expect revenue to be approximately $0.3 million and $5.7 million, respectively.
- For the three months and year ended December 31, 2023, we expect operating expenses to be approximately $24 million to $26 million and $120 million to $122 million, respectively, inclusive of a $21.3 million goodwill impairment that was recorded within operating expenses in the three months ended June 30, 2023.

The foregoing estimates as of and for the three months and year ended December 31, 2023, in each case, are preliminary. The Company is in the process of finalizing the actual results of operations for the three months and year ended December 31, 2023 and therefore final results are not yet available. These preliminary estimates are based solely upon information available to the Company as of the date of this Current Report on Form 8-K and actual results may differ from these estimates subject to the completion of the Company's quarter- and year-end closing procedures, final adjustments and developments that may arise between now and the time the financial results for the three months and year ended December 31, 2023 are finalized. Additionally, the Company's independent registered public accounting firm has not yet completed its audit of the Company's consolidated financial statements for the year ended December 31, 2023. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of and for the three months and year ended December 31, 2023. Investors should refer to the actual results included in the Company's unaudited condensed consolidated financial statements for the three months ended December 31, 2023 and the audited consolidated financial statements for the year ended December 31, 2023 once they become available upon filing of the Company's Annual Report on Form 10-K.

The Company's independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to these preliminary estimates and, accordingly, does not express an opinion or any other form of assurance about them.

The information furnished under this Item 2.02 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Information.

Also on February 27, 2024, the Company filed a preliminary prospectus supplement with the Securities and Exchange Commission under its effective shelf registration statement on Form S-3 (Registration No. 333-267043) (the "Preliminary Prospectus Supplement") in connection with a proposed registered underwritten public offering of common stock.

The Preliminary Prospectus Supplement contains information relating to recent developments concerning the Company's business and includes the following disclosure:

Our Business Model

Our business model is to use our platform for rapid creation of biologic drug candidates by:

Establishing partnerships with stakeholders in the drug discovery and development life cycle: We create drug candidates with partners, including pharmaceutical and biotechnology companies who are responsible

for preclinical and clinical testing of biologic candidates generated through our platform. Our partnerships will provide us with the opportunity to participate in the future success of the biologic candidates generated utilizing our platform, including through potential clinical, regulatory and commercial milestone payments as well as royalties on net sales of approved products. We aim to assemble economic interests in a diversified portfolio of partnered pipeline assets of biologics across multiple indications.

Developing our own proprietary asset pipeline: We aim to create therapeutic assets comprising our own internal program pipeline. With the ability to find targets and develop potential best-in-class assets, we intend to develop promising assets to value inflection points, anywhere from preclinical validation through clinical trials, before partnering or selling them. Accordingly, we may enter into clinical trials and/or manufacturing partnerships to advance specific therapeutic assets to target such value inflection points. We believe that by developing our own pipeline, we will create optionality for enhanced monetization and validation of our platform.

Our evolving business model is underpinned by a strategic shift towards diversifying our program portfolio through both partnered drug creation programs and internal asset development programs. Our approach is to balance the portfolio between partnered programs that broaden our reach into various indications and provide R&D and upfront funding, and internal programs for which we have more control and the potential for partnerships or asset sales that provide more significant economic returns. The cornerstone of this business model evolution lies in the diversification of risk and potential return on investment. Engaging in drug creation partnerships may enable us to reach broader indications and markets, whereas internal asset development may be more advantageous in terms of greater control over program selection, development timeline, and return on investment. Our dual-faceted model not only secures a focused set of indications but also gives us greater optionality, enhancing our ability to pivot and adapt as the programs progress. We believe we will grow and diversify our portfolio of programs through our model, ultimately driving innovation and delivering value for all stakeholders.

Our Partnerships

We structure our partnerships as drug creation agreements with options for our partners to license intellectual property rights to the biological assets we create after completion of the drug creation phase. The primary goal of the drug creation phase includes target creation, lead or candidate creation, and development or optimization of a lead candidate or set of lead candidates. For the drug creation phase, partners may request a scope that includes, but is not limited to, a specified disease area, a target for creation of a new biologic, or supply a specified lead candidate for AI-driven optimization. For most partnerships, we expect to negotiate and agree to downstream economic terms of any license to our intellectual property rights before initiating the drug creation phase. We anticipate that these drug creation agreements may provide us with rights to receive payments upon the achievement of various clinical, regulatory and commercial milestones for the applicable product candidates, as well as royalties on net sales at least during the marketing exclusivity period of candidates approved for commercialization.

Active Programs

We define “Active Programs” as drug creation programs that are subject to ongoing technology development activities intended to determine if the program can be pursued by our partner for future clinical development, as well as any program for which our partner obtains and maintains a license to our technology to advance the program after completion of the drug creation phase. There is no assurance, however, that our partners will advance any drug candidates that are currently the subject of Active Programs into further preclinical or clinical development or that our partners will elect to license our technologies upon completion of the drug creation phase in a timely manner, or at all.

As of December 31, 2023, our Active Programs are as follows:

Partner	Contract Date	Active Programs	Therapeutic Area
PrecisionLife	December 2023	5	Undisclosed
Almirall	November 2023	2	Dermatology
AstraZeneca	November 2023	1	Oncology
Undisclosed	July 2023	1	Undisclosed
Undisclosed	March 2023	1	Undisclosed
Merck	January 2022	3	Undisclosed
Merck	December 2019	1	Undisclosed
Alpha Cancer Technologies	August 2019	1	Oncology
SFJ Pharmaceuticals	April 2019	1	Hematology
Active Programs		16	

Our Integrated Drug Creation platform is primarily utilized in our partnerships for drug creation across indications using AI to simultaneously optimize multiple drug characteristics that may be important to development and therapeutic benefit. One of our Active Programs with an undisclosed partner is leveraging our platform capabilities to optimize pharmacokinetic properties for a Phase II candidate and one of our Active Programs with an undisclosed partner is leveraging our platform capabilities including our antibody library. We also have three Active Programs focused on our legacy model of developing production cell lines for drug candidates that our partners are developing. Two of these legacy cell line development Active Programs are preclinical and one is in Phase 3 clinical development (PhaseBio Pharmaceuticals' drug candidate, bentracimab, assumed by SFJ Pharmaceuticals, Inc. in January 2023).

We have negotiated license agreements, or expected to negotiate license agreements upon completion of certain drug creation activities, with potential downstream milestone payments and royalties for all Active Programs. We have not negotiated terms for a sufficient number of royalty- and milestone-bearing licenses, however, to enable us to make accurate predictions regarding our potential revenue and financial performance.

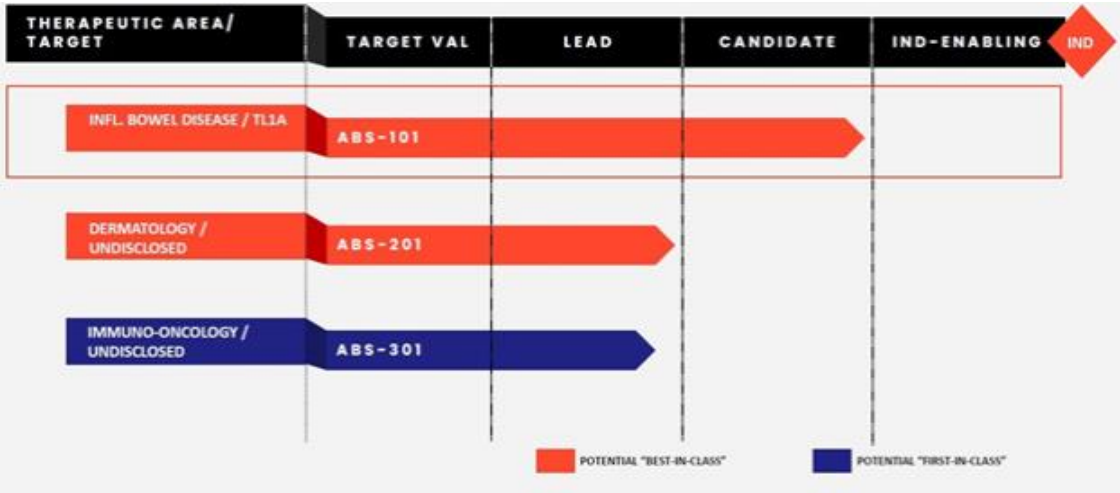
Internal Pipeline

Our biologics pipeline reflects our differentiated capabilities in *de novo* antibody creation, multi-parameteric lead optimization, and reverse immunology. We're developing a diversified portfolio of internal programs with a focus on cytokine biology as we scale our Integrated Drug Creation platform and strive to impact millions of lives.

Internal Asset Programs

As of December 31, 2023, we have identified three wholly-owned internal asset programs focusing on cytokine biology as well as several undisclosed internal pipeline programs under evaluation.

Program Name	Target Description
ABS-101	Candidate targeting TL1A in inflammatory bowel disease
ABS-201	Lead and optimization stage for an undisclosed therapeutic target in dermatology
ABS-301	Lead and optimization stage for an undisclosed therapeutic target in immuno-oncology



We are aware of clinical stage assets targeting TL1A that are being developed by Merck, Roche and Sanofi. For purposes of comparing the anticipated attributes of ABS-101 to these competitive product candidates, we generated putative clinical competitor molecules and performed a head to head comparison against several potential ABS-101 molecules. In these preclinical studies, ABS-101 potential candidates exhibited properties consistent with a potentially superior product profile by demonstrating equal or superior potency data from multiple biophysical and cellular assays, in addition to improved developability properties. We believe these attributes support the program's potential to create an efficacious candidate conducive to subcutaneous dosing. Furthermore, in vitro and preliminary in vivo PK studies confirm the potential for extended half-life, supporting the objective for significantly improved dosing intervals. While we are encouraged by these preclinical results, we cannot assure you that similar results will be obtained in clinical studies of ABS-101. Additionally, while we endeavored to create molecules with the same attributes as those of competitive product candidates under development, we cannot assure you that the molecules we created are similar or better than those being developed by our competitors, nor can we assure you that direct comparisons of our clinical product candidate to those of our competitors will produce similar results.

In February 2024 we initiated IND-enabling studies for ABS-101 to further evaluate certain properties of ABS-101. Based on these IND-enabling studies, we plan to submit a IND in the first quarter of 2025 and potentially initiate a Phase 1 clinical trial in the first half of 2025.

Government Regulation

Biologics License Application (BLA) Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product candidate for one or more indications. The BLA must include all relevant data available from preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product candidate's chemistry, manufacturing, controls, and proposed labeling, among other things. Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a significant application user fee to the FDA, unless a waiver or exemption applies, which is adjusted on an annual basis. The FDA has sixty days from the applicant's submission of a BLA to either issue a refusal to file letter or accept the BLA for filing, indicating that it is sufficiently complete to permit substantive review. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval, and may require additional preclinical, clinical or other studies before it accepts the filing.

Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may be significantly extended by

FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product candidate is safe, pure and potent for its intended use, and whether the facility in which it is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, and purity. The FDA may convene an advisory committee, typically a panel that includes clinicians and other experts, to provide clinical insight on applications which present difficult questions of safety or efficacy and to review, evaluate and recommend whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the facility or facilities where the product is manufactured to determine whether the facilities comply with cGMPs. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically audit data from clinical trials to ensure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies and/or other significant and time-consuming requirements related to preclinical studies and manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even if such data and information is submitted, the FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for a particular indication(s) and may entail limitations on the indicated uses for which such product may be marketed. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. The FDA may also place other conditions on approvals including the requirement of a Risk Evaluation and Mitigation Strategy (REMS), to assure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Any of these limitations on approval or marketing could

restrict the commercial promotion, distribution, prescription or dispensing of products. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding the Company's preliminary unaudited financial results as of and for the three months and year ended December 31, 2023, the Company's business model, partnership opportunities, the timing of drug creation agreements and potential related payments and milestones, active programs and potential revenue and the potential development or timelines associated with our internal programs. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond the Company's control, include the risk that our actual financial results for the three months and year ended December 31, 2023 differ from the estimates presented in this Current Report on Form 8-K; as well as the other risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. The Company disclaims any obligation to update these forward-looking statements.

SIGNATURE

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.

Absci Corporation

Date: February 27, 2024

By: /s/ Sean McClain
Sean McClain
Founder and CEO