

**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: November 2, 2023
(Date of earliest event reported)

Orogenics, Inc.

(Exact name of registrant as specified in its charter)

FL
(State or other jurisdiction
of incorporation)

001-32188
(Commission
File Number)

59-3410522
(IRS Employer
Identification Number)

4902 Eisenhower Boulevard, Suite 125
Tampa, FL
(Address of principal executive offices)

33634
(Zip Code)

813-286-7900
(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))

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	OGEN	NYSE American

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 8.01 Other Events.

On November 2, 2023, Orogenics, Inc (“Orogenics” or the “Company”) issued a letter to its shareholders updating the shareholders on the Company’s business.

A copy of the letter is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 2, 2023.
104	Cover page Interactive Data File (embedded in the cover page formatted in Inline XBRL)

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on November 2, 2023.

ORAGENICS, INC. (Registrant)

BY: /s/ Janet Huffman

Janet Huffman, Chief Financial Officer

Orogenics Issues Update to Shareholders**TAMPA, Fla. (November 2, 2023)**–

Fellow Shareholders,

As our annual meeting date approaches and in response to valuable feedback from our shareholders, I believe it important to highlight and summarize some of the information in our proxy statement regarding the proposed increase in our authorized shares as well as our cost-saving efforts.

Odyssey Asset Purchase

On October 5, 2023, we proudly announced that we had entered into an agreement to acquire Odyssey Health, Inc.'s lead assets. This transaction is expected to close in December 2023, subject to various closing conditions. We view this acquisition as a strategic move that holds significant potential for enhancing shareholder value. The assets are related to Odyssey's proprietary neurological drug therapies, including their proprietary formulation and nasal delivery system. The assets include drug candidates for treating mild traumatic brain injury, also known as concussion, and for treating Niemann Pick Disease Type C. We anticipate that the alignment between these assets and our existing nasal delivery platform could significantly expand our reach to a broader market. We believe that our ongoing intranasal vaccine product development, coupled with the success of this acquisition, could positively impact both the neurological and infectious disease markets.

Concussions represent an unmet medical need affecting millions globally. In the U.S. alone, an estimated 5 million concussions occur annually, with up to 50% going unreported. The global market for concussion treatment was valued at \$6.9 billion in 2020, with a forecasted growth to \$8.9 billion by 2027, according to Grandview Research.

Niemann Pick Type C Disease is a rare neurodegenerative genetic disorder with a growing market, projected to increase from \$128 million in 2022 to \$188 million in 2031 across the U.S., Germany, and the U.K.

The potential acquisition of the Odyssey assets also introduces a team of talented scientists who could greatly enhance our current research and development efforts at Orogenics, particularly in the fields of infectious and neurological drug therapies and intranasal drug delivery systems.

Proposal 3 of our 2022 Annual Meeting

We've received numerous requests for further clarification regarding Proposal 3 within the seven items on our annual meeting agenda. Currently, Orogenics has an aggregate of 54,166,666 shares of authorized capital stock, comprised of 4,166,666 shares of common stock with a par value of \$0.001 and 50,000,000 shares of preferred stock with no par value.

Out of the 4,166,666 authorized common shares, approximately 2.5 million have been issued, with around 383,000 reserved for stock options and warrants. The remaining 1.2 million shares are available for issuance or capital-raising efforts.

The closing of the Odyssey acquisition is conditioned, among other things, on the increase of our authorized common stock. If Odyssey were to convert all the Series F Convertible Preferred Stock we will issue to Odyssey, assuming the successful closing of the acquisition, we would be required to issue 8 million shares of common stock, which we cannot do without increasing our authorized common stock.

Furthermore, as discussed in our most recent Form 10-Q filed with the SEC on August 11, 2023, we have a need for additional capital to support ongoing research and development. While we explore various funding avenues, including non-dilutive and dilutive opportunities, increasing the authorized shares of common stock is essential for substantial capital infusion through equity sales.

We understand concerns about potential dilution and its impact on shareholders. It is crucial to note that increasing authorized shares enables us to act quickly as financing opportunities may arise. As of this letter's date, there are no immediate plans or agreements to issue the additional shares of Common Stock proposed, except those related to the Odyssey asset purchase. Our goal is to position the company for success, facilitating the Odyssey asset purchase and future financing needs.

Ongoing Partnerships and Progress

Regarding our current contracts and partnerships with Inspirevax and CQDM, we remain dedicated to these strategic alliances and the development of a successful nasal delivery system for our vaccine candidate. Biotech research and development is an ongoing process requiring time, dedication, and financial commitment.

In recent months, we've made tough yet necessary decisions to reduce expenses and conserve cash resources to prioritize our vaccine product's research and development. We maintain our optimism for the future of our vaccine candidate while working to secure the required additional capital for our continued progress. We believe in the potential of intranasal drug therapies and devices, and we will provide substantial updates as they unfold.

Thank you for your continued support of Orogenics. I encourage you to vote at the annual meeting and support our mission to impact even more lives and improve human health in meaningful ways. Proxy materials can be found on the internet at www.cstproxy.com/orogenics/2023 or at the SEC website at www.sec.gov.

Kimberly Murphy

/s/ Kimberly Murphy

Chief Executive Officer and President
November 2, 2023

Contacts:

Orogenics, Inc.
Janet Huffman, Chief Financial Officer
813-286-7900
jhuffman@orogenics.comLHA Investor Relations
Tirth T. Patel
212-201-6614
tpatel@lhai.com

Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 including without limitation statements regarding the ability of the Company to successfully close the Odyssey acquisition, the ability of the Company to timely and successfully achieve the anticipated benefits of acquiring the Odyssey assets and the Company’s future performance, business prospects, events and product development plans. These forward-looking statements are based on management’s beliefs and assumptions and information currently available. The words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project” and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to, the following: the Company’s ability increase its authorized shares of Common Stock; the Company’s ability to obtain a quorum at future shareholders meetings; the Company’s ability to satisfy the closing conditions to the Odyssey acquisition; the Company’s ability to advance the development of its product candidates under the timelines and in accord with the milestones it projects; the Company’s ability to obtain funding, non-dilutive or otherwise, for the development of its product candidates, whether through its own cash on hand, or another alternative source; the regulatory application process, research and development stages, and future clinical data and analysis relating to vaccines and antibiotics, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the potential application of our vaccine candidate to variants and other coronaviruses; the Company’s ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to COVID-19 immunization and therapeutic treatments and demand for vaccines and antibiotics; the Company’s expectations as to the outcome of preclinical studies, nasal administration, transmission, manufacturing, storage and distribution; other potential adverse impacts due to the global COVID-19 pandemic, such as delays in regulatory review, interruptions to manufacturers and supply chains, adverse impacts on healthcare systems and disruption of the global economy; and general economic and market conditions and risks, as well as other uncertainties described in our filings with the U.S. Securities and Exchange Commission. All information set forth in this communication is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this communication and not place undue reliance on such statements. We do not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, should circumstances change, except as otherwise required by law.
