# 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): **May 11, 2023**

# RVL Pharmaceuticals plc

(Exact name of registrant as specified in its charter)

| **Ireland** | **001-38709** | **Not Applicable** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **400 Crossing Boulevard**<br>**Bridgewater, NJ** | **08807** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

(Registrant's telephone number, including area code): **(908) 809-1300**

**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 |
|---|---|---|
| Ordinary Shares | RVLP | 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 May 11, 2023, RVL Pharmaceuticals plc (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release issued by RVL Pharmaceuticals plc on May 11, 2023 |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL) |

**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.

**RVL PHARMACEUTICALS PLC**

Dated: May 11, 2023

By: /s/ Brian Markison
Brian Markison
Chief Executive Officer

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

**RVL Pharmaceuticals plc Reports First Quarter 2023 Financial Results; Provides Commercial Update**

*-- First quarter 2023 UPNEEQ® net product sales grew 49%, or $2.9 million, over the prior year period to $8.8 million --*

*-- Enhanced operating leverage with a 32%, or $7.9 million, reduction in first quarter 2023 total operating expenditures from the prior year --*

*-- Majority of aesthetic orders in the first quarter, or 54%, represented reorder activity --*

*-- Approximately 4,800 cumulative unique medical aesthetics practices had placed orders for UPNEEQ through the end of the first quarter, a 12% increase from prior quarter end --*

*-- UPNEEQ Won "Best Eye Drop for Drooping Lids" NewBeauty in 13th Annual Beauty Awards, selected from among 10,000 entrants --*

**BRIDGEWATER, N.J., May 11, 2023 –** RVL Pharmaceuticals plc (Nasdaq: RVLP) ("RVL" or the "Company"), a specialty pharmaceutical company focused on the commercialization of UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or droopy or low-lying eyelids, in adults, today announced financial results and business highlights for the three months ended March 31, 2023.

"RVL is off to a great start on the year. Our one-of-a-kind product continues to exhibit year-over-year growth as we leverage our cost base for improved efficiency. Our multi-channel strategy is delivering favorable results. In fact, monthly pharmacy prescriptions reached an all-time high during the first quarter of 2023, despite the absence of personal promotional support. Additionally, momentum in aesthetics continued, with growth in the percentage of reorders and in new account openings during the quarter. We believe we have barely scratched the surface of the potential for this amazing product," stated Brian Markison, Chief Executive Officer of RVL.

"We believe the July rollout of Elevate, our next-generation e-commerce portal, will be a powerful step that will broaden our reach, improve the customer experience and facilitate enhanced access to UPNEEQ – all while providing us with data and analytics to further inform our marketing initiatives," continued Markison.

"The social proof behind UPNEEQ continues to build, as evidenced by being selected the winner as 'Best Eye Drop for Drooping Lids' in the NewBeauty 13th Annual Beauty Awards. This is our second consecutive win, following our award last year from NewBeauty for the 'Best Innovation,'" concluded Markison.

**First Quarter 2023 Financial Highlights**

- UPNEEQ net product sales were $8.8 million, an increase of $2.9 million, or 49%, over the first quarter of 2022.
    - Approximately 4,800 cumulative unique medical aesthetics practices had placed orders for UPNEEQ at quarter end, an increase of 12% from the end of 2022.
    - Approximately 19,900 cumulative unique pharmacy-paid prescribers at quarter end, an increase of 8% compared to the end of 2022.
    - At quarter end, the optometry and ophthalmology customer base accounted for 68% and 32%, respectively, of its total unique eye care prescriber base.
- Net loss was $(11.6) million, compared to a net loss of $(6.8) million in the prior year period. Adjusted EBITDA[1] loss was $(8.7) million, compared to an Adjusted EBITDA loss of $(18.9) million in the first quarter of 2022.
- At March 31, 2023, the Company had cash and cash equivalents of $32.6 million and senior secured indebtedness with aggregate principal maturities of $70.7 million.

**First Quarter 2023 Financial Results**

Net product sales, relating entirely to sales of UPNEEQ, increased by $2.9 million to $8.8 million for the three months ended March 31, 2023, as compared to $5.9 million for the three months ended March 31, 2022, primarily due to a year-over-year increase in sales volume reflecting expanded commercialization into the medical aesthetics market in February 2022 and into telemedicine in the second half of 2022.

Royalty and licensing revenues were $15.5 million in the three months ended March 31, 2022, reflecting milestone revenues recognized under our agreement with Santen. There was no royalty and licensing revenue in the three months ended March 31, 2023.

Total revenues decreased by $12.6 million to $8.8 million in the three months ended March 31, 2023, as compared to $21.4 million in the three months ended March 31, 2022, primarily due to the absence of licensing revenue from Santen during 2023, partially offset by a year-over-year increase in net product sales. For the three months ended March 31, 2023, one customer accounted for 21% of the Company's total revenues.

Total cost of goods sold increased by $0.2 million to $2.3 million in the three months ended March 31, 2023, as compared to $2.1 million in the three months ended March 31, 2022. The year-over-year increase in cost of goods sold was primarily driven by $0.3 million in higher product costs for UPNEEQ due to higher sales volume.

[1] Adjusted EBITDA is a non-GAAP financial measurement, see "Presentation of Non-GAAP Financial Measures."

Gross profit percentage decreased to 74% in the three months ended March 31, 2023, as compared to 90% in the 2022 period, largely due to unique licensing revenue from Santen recognized during the 2022 period. Excluding licensing revenues, gross profit percentage from net product sales was 74% and 64% in the 2023 and 2022 periods, respectively, reflecting lower royalty expense, inclusive of contingent earn out obligations, and improved overhead absorption driven by higher volumes.

Selling, general and administrative expenses decreased by $7.6 million to $16.2 million in the three months ended March 31, 2023, as compared to $23.8 million in the three months ended March 31, 2022. The year-over-year decrease in selling, general and administrative expenses was primarily driven by (i) $5.6 million in lower net compensation and training costs primarily relating to the absence of an eye care salesforce in the 2023 period, (ii) $0.9 million in lower legal, insurance and other professional fees, (iii) $0.5 million in lower share-based compensation, and (iv) $0.4 million in lower marketing expenses for UPNEEQ.

Research and development expenses decreased by $0.3 million to $0.6 million in the three months ended March 31, 2023, as compared to $0.9 million in the three months ended March 31, 2022. The year-over-year decrease in research and development expenses primarily reflects $0.2 million in lower share-based compensation expense.

Total other non-operating activities were a source of income of $1.3 million and $1.5 million in the three months ended March 31, 2023, and 2022, respectively. Non-operating income in each of the 2023 and 2022 periods was primarily attributable to the receipt of an aggregate of $5.0 million in cash from Alora related to contingent milestone payments earned in connection with the sale of our legacy business in 2021. Non-operating income in the 2023 and 2022 periods was partially offset by aggregate losses recognized from the change in fair value of the Company's debt and warrant liability.

Net loss increased by $(4.8) million to an $(11.6) million loss in the three months ended March 31, 2023, as compared to a $(6.8) million loss in the three months ended March 31, 2022. Adjusted EBITDA loss decreased by $10.2 million to an $(8.7) million loss in the three months ended March 31, 2023, as compared to an $(18.9) million loss in the three months ended March 31, 2022.

**Liquidity**

At March 31, 2023, the Company had cash and cash equivalents of $32.6 million and senior secured indebtedness with aggregate principal maturities of $70.7 million, which are reflected on its balance sheet at fair value of $56.3 million.

**Presentation of Non-GAAP Financial Measures**

In addition to our results determined in accordance with accounting principles generally accepted in the United States of America ("GAAP") throughout this press release, we also present Adjusted EBITDA loss, which is a non-GAAP financial measurement. Adjusted EBITDA loss represents earnings before interest, taxes, depreciation and amortization (or "EBITDA") adjusted for (i) non-operating income or expense and (ii) the impact of certain non-cash, non-recurring or other items that are included in net loss and EBITDA that we do not consider indicative of our ongoing operating performance. In particular, our measurement of Adjusted EBITDA loss excludes the following from EBITDA: licensing-related revenues, net of transaction costs; divestiture-related contingent milestone payments, net of fees; changes in the fair value of our debt and interest expense and warrant liability recognized through earnings; gains or losses on the sale of product rights; impairments of intangible assets; asset disposal charges; debt financing costs; share-based compensation expense; severance expenses; foreign currency translation; legal settlements and expenses and other expenses.

We use Adjusted EBITDA loss for business planning purposes, in assessing our performance and in measuring our performance relative to that of our competitors. We also believe that Adjusted EBITDA loss provides investors with useful information to understand our operating results and analyze financial and business trends on a period-to-period basis. Adjusted EBITDA loss has important limitations as an analytical tool, however, and you should not consider it in isolation or as a substitute for analysis of our results as reported under GAAP. Adjusted EBITDA loss is not intended to replace, and should not be considered superior to, the presentation of our financial results in accordance with GAAP. Our definition of Adjusted EBITDA loss may differ from similar measures reported by other companies and may not be comparable to other similarly titled measures. Adjusted EBITDA loss is reconciled from net loss, the most comparable GAAP financial measure, in the attached table "RVL Pharmaceuticals plc - GAAP to Non-GAAP Reconciliations" at the end of this press release.

**Forward-Looking Statements**

This press release includes statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." The Company's actual results may vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms "believes," "expects," "may," "will," "should," "seeks," "projects," "approximately," "intends," "plans," "targets," "estimates" or "anticipates," or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, its results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and other events, particularly relating to sales of UPNEEQ, U.S. Food and Drug Administration ("FDA") and other regulatory applications, approvals and actions, the rollout of Elevate, our next generation e-commerce portal and the expansion into telemedicine, the continuation of historical trends, our ability to manage costs and service our debt and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: UPNEEQ's ability to reach market acceptance by clinicians and patients; our ability to successfully commercialize UPNEEQ; our customers' willingness to pay the price we charge for UPNEEQ; the results of our marketing and sales expenditures; our dependence on third-party suppliers and distributors for UPNEEQ; UPNEEQ's ability to produce its intended effects; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; and other risks and uncertainties more fully described in the "Risk Factors" section of our Annual Report on Form 10-K filed on March 20, 2023, and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this press release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

**Conference Call**

As previously announced, RVL management will host its first quarter 2023 financial results conference call as follows:

| | |
|---|---|
| Date: | Thursday, May 11, 2023 |
| Time: | 8:30 a.m. ET |
| Toll free (U.S.): | 800-579-2543 |
| International: | 785-424-1789 |
| Webcast (live and replay): | ir.rvlpharma.com under the “Investors & News” section |

A replay of the conference call will be available for one week after the call's completion by dialing 800-938-0996 (U.S.) or 402-220-1540 (International) and entering conference call ID RVLQ123. The webcast will be archived for one year at the aforementioned URL.

**IMPORTANT SAFETY INFORMATION**

**INDICATION**

UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is indicated for the treatment of acquired blepharoptosis in adults.

**WARNINGS AND PRECAUTIONS**

- Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of ptosis with decreased levator muscle function and/or other neurologic signs.
- Alpha-adrenergic agonists as a class may impact blood pressure. Advise UPNEEQ patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use UPNEEQ with caution in patients with cerebral or coronary insufficiency or Sjögren’s syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.

- UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop.
- Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

**ADVERSE REACTIONS**

Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

**DRUG INTERACTIONS**

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as betablockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.

- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

**About RVL Pharmaceuticals plc**

RVL Pharmaceuticals plc is a specialty pharmaceutical company focused on the commercialization of UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or low-lying eyelid, in adults. UPNEEQ is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis.

**Investor and Media Relations for RVL Pharmaceuticals plc**

Lisa M. Wilson
In-Site Communications, Inc.
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-Financial Tables Follow-

**RVL Pharmaceuticals plc**
**Unaudited Condensed Consolidated Balance Sheets**
(in thousands)

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 32,640 | $ 44,543 |
| Accounts receivable and other receivables | 1,879 | 3,031 |
| Inventories, net | 213 | 784 |
| Prepaid expenses and other current assets | 3,620 | 8,617 |
| Total current assets | 38,352 | 56,975 |
| Property, plant and equipment, net | 2,487 | 1,276 |
| Operating lease assets | 522 | 512 |
| Indefinite-lived intangible assets | 13,900 | 13,900 |
| Goodwill | 55,847 | 55,847 |
| Total assets | $ 111,108 | $ 128,510 |
| | | |
| **Liabilities and Shareholders' Equity** | | |
| Current liabilities: | | |
| Trade accounts payable | $ 2,630 | $ 2,407 |
| Accrued liabilities | 9,268 | 15,395 |
| Current portion of debt ($3,261 measured at fair value and representing $3,533 of aggregate unpaid principal at March 31, 2023) | 4,150 | 1,432 |
| Current portion of obligations under finance leases | 11 | 10 |
| Current portion of lease liability | 306 | 435 |
| Income taxes payable - current portion | 43 | 44 |
| Total current liabilities | 16,408 | 19,723 |
| Long-term debt (measured at fair value and representing $67,133 and $75,000 of aggregate unpaid principal at March 31, 2023 and December 31, 2022, respectively) | 53,039 | 55,500 |
| Warrant liability | 1,274 | 1,951 |
| Long-term portion of obligation under finance leases | 15 | 18 |
| Long-term portion of lease liability | 229 | 94 |
| Income taxes payable - long term portion | 71 | 70 |
| Deferred taxes | 72 | 61 |
| Total liabilities | 71,108 | 77,417 |
| Shareholders' equity: | | |
| Ordinary shares | 993 | 992 |
| Additional paid in capital | 619,841 | 619,323 |
| Accumulated deficit | (580,834) | (569,222) |
| Total shareholders' equity | 40,000 | 51,093 |
| Total liabilities and shareholders' equity | $ 111,108 | $ 128,510 |

**RVL Pharmaceuticals plc**
**Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss**
(in thousands, except share and per share data)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Net product sales | $ 8,832 | $ 5,944 |
| Royalty and licensing revenue | — | 15,500 |
| Total revenues | 8,832 | 21,444 |
| Cost of goods sold | 2,299 | 2,144 |
| Gross profit | 6,533 | 19,300 |
| Selling, general and administrative expenses | 16,198 | 23,834 |
| Research and development expenses | 626 | 862 |
| Total operating expenses | 16,824 | 24,696 |
| Operating loss | (10,291) | (5,396) |
| Interest expense and amortization of debt discount | 26 | 985 |
| Change in fair value of debt and interest expense | 7,349 | 1,044 |
| Change in fair value of warrants | (677) | 4,508 |
| Other non-operating income, net | (5,435) | (5,037) |
| Total other non-operating income | 1,263 | 1,500 |
| Loss before income taxes | (11,554) | (6,896) |
| Income tax expense (benefit) | 58 | (75) |
| Net loss | $ (11,612) | $ (6,821) |
| Change in fair value of debt due to change in credit risk, net of tax | — | (1,700) |
| Comprehensive loss | $ (11,612) | $ (8,521) |
| Loss per ordinary share: | | |
| Basic and diluted | $ (0.12) | $ (0.08) |
| Weighted average ordinary shares outstanding: | | |
| Basic and diluted | 99,321,304 | 83,489,900 |

**RVL Pharmaceuticals plc**
**Unaudited Condensed Consolidated Statements of Cash Flows**
(in thousands)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (11,612) | $ (6,821) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 93 | 89 |
| Share compensation | 499 | 1,209 |
| Change in fair value of debt | 5,134 | (400) |
| Change in fair value of warrants | (677) | 4,508 |
| Deferred income tax benefit | 11 | 9 |
| Gain on sale of fixed and leased assets | (79) | (37) |
| Amortization of deferred financing and loan origination fees | — | 967 |
| Change in operating assets and liabilities: | | |
| Accounts receivable and other receivables | 1,152 | (15,439) |
| Inventories, net | 571 | — |
| Prepaid expenses and other current and non-current assets | 4,998 | 420 |
| Trade accounts payable | 224 | 955 |
| Accrued and other current liabilities | (6,132) | 1,264 |
| Net cash used in operating activities | (5,818) | (13,276) |
| **Cash Flows from Investing Activities:** | | |
| Proceeds from sale of fixed and leased assets | 79 | 37 |
| Purchases of property, plant and equipment | (1,304) | (27) |
| Net cash (used in) provided by investing activities | (1,225) | 10 |
| **Cash Flows from Financing Activities:** | | |
| Payments on finance lease obligations | (2) | (2) |
| Payments on insurance financing loan | (544) | (897) |
| Payments for taxes related to net share settlement of share-based awards | (72) | (57) |
| Proceeds from issuance of ordinary shares under the ESP Plan | 92 | 119 |
| Debt repayments | (4,334) | — |
| Net cash used in financing activities | (4,860) | (837) |
| Net change in cash and cash equivalents | (11,903) | (14,103) |
| Cash and cash equivalents, beginning of period | 44,543 | 40,444 |
| Cash and cash equivalents, end of period | $ 32,640 | $ 26,341 |

**RVL Pharmaceuticals plc**
**GAAP to Non-GAAP Reconciliations**
**Adjusted EBITDA (Unaudited)**
(in thousands)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Net loss | $ (11,612) | $ (6,821) |
| Interest expense and amortization of debt discount | 26 | 985 |
| Income tax expense (benefit) | 58 | (75) |
| Depreciation and amortization expense | 93 | 89 |
| EBITDA | (11,435) | (5,822) |
| Licensing-related revenues, net of transaction costs[(1)] | — | (15,000) |
| Divestiture-related contingent milestone payments, excluding fees[(2)] | (5,000) | (5,000) |
| Debt financing costs[(3)] | 575 | 150 |
| Change in fair value of debt and interest expense[(4)] | 7,349 | 1,044 |
| Change in fair value of warrants[(4)] | (677) | 4,508 |
| Share-based compensation expense | 499 | 1,209 |
| Foreign currency translation | 34 | 14 |
| Adjusted EBITDA Loss | $ (8,655) | $ (18,897) |

(1) - 2022 includes $15,500 in licensing revenue recognized in connection with an amendment of our License Agreement with Santen, effective March 31, 2022, net of a $500 transaction fee expense classified in selling, general and administrative expenses.

(2) - Relates to contingent gains related to milestone payments earned subsequent to the sale of our legacy business to Alora Pharmaceuticals.

(3) - 2023 relates to $575 in mandatory debt repayment fees, classified in selling, general and administrative expenses, incurred as a result of our receipt of a contingent milestone payment. 2022 relates to $150 in consent fees, classified in selling, general and administrative expenses, incurred with our lendor upon the issuance of waivers of mandatory repayments of debt following receipt of a contingent milestone payment.

(4) - Our senior secured notes issued under our Note Purchase Agreement, a material component of long-term debt, and our warrant liabilities, a material component of total liabilities have each been measured and carried at fair value since their issuance in October 2021. Changes in the fair value of debt and warrants are accounted for at fair value, inclusive of related accrued interest expense in respect of debt, and are presented as periodic gains or losses in our consolidated statements of operations and comprehensive loss.